

# **EXHIBIT 35**

<b>Food and Drug Administration Office of Regulatory Affairs</b> <b>Collection Report</b> <b>For Sample Number: 453913</b> An accurate reproduction of the original electronic record as of 03/01/2010					
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<b>Flag</b>	<b>Flag Remarks</b>				
<b>Episode Number</b>	<b>Origin</b>	<b>Basis</b>	<b>Sample Type</b>	<b>FIS Smpl Num</b>	<b>Status</b>
	Domestic	Other-Survl	Official	0885198	Completed
<b>FEI</b>	<b>Date Collected</b>	<b>Product Code</b>	<b>Responsible Firm</b>	<b>PAC</b>	<b>Hours</b>
1610608 2244683	02/15/2008	63FCA06	Manufacturer	56008A	5.5
<b>Compliance Num</b>	<b>Country of Origin</b>				
	United States				
<b>Related Smpl Num</b>	<b>Position Class</b>	<b>Sampling District</b>	<b>NDC Number</b>	<b>Permit Number</b>	<b>Storage Rqrmnt.</b>
	INV	ATL-DO	62794-145-10		Ambient
<b>Dealer is Consumer</b>	<b>Crx/DEA Schedule</b>	<b>Recall Num</b>	<b>Consumer Compl. Num</b>	<b>Brand Name</b>	
No				DIGITEK (digoxin tablets, USP) 125 mcg (0.125 mg)	

**Product Description**

Digoxin Tablets, USP packed in a white plastic bottle w/white screw-on top, NDC 62794-145-10.

**Product Label**

See continuation.

**Reason for Collection**

Sample collected as part of the FY 2008 Low Cost Generic Drug  
 Sample Survey (CP 7356.008) FACTS Assignment #896749 ORA  
 concurrence #2008101702.

**MFG Codes**

70737A1

**Expiration Date**

SEP 09

<b>Firm Legal Name</b>	<b>Address</b>	<b>Type of Firm</b>	<b>Firm FEI</b>	<b>FCE</b>
(b) (4)	(b) (4)	Dealer	(b) (4)	
UDL Laboratories, Inc	12720 Dairy Ashford Rd Sugar Land, TX 77478-2844 US	Manufacturer	1610608	
Aclavis Totowa LLC	101 E Main St Little Falls, NJ 07424-5608 US	Manufacturer	2244683	
<b>Size of Lot</b>	<b>Est. Value</b>	<b>Rept Type</b>	<b>Carrier Name</b>	<b>Date Shipped</b>
12 bottles	\$ (b) (4)	FDA484		

**Description of Sample**

Sample consists of 1 bottle of DIGITEK (digoxin tablets, USP) 125 mcg (0.125 mg) containing 1000 tablets. NDC 62794-145-10.

**Method of Collection**

The sample bottle was collected randomly from the warehouse line.

**How Prepared**

See continuation.

**Collector's Identification on Package and/or Label**

"453913 02/15/08 ARB"

**Collector's Identification on Seal**

"453913 02/15/08 April R. Bowen"

**Sample Delivered To**

FedEx

**Date Delivered**

02/19/2008

**Orig C/R & Records To**

NWJ-DO

**Lab w/Split Sample**

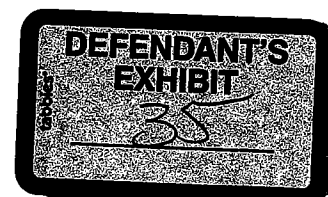
0

**Lab**

NRL

Date: 03/01/2010

Page: 1 of 3



**Food and Drug Administration Office of Regulatory Affairs**  
**Collection Report**

For Sample Number: 453913

This is an accurate reproduction of the original electronic record as of 03/01/2010

Document Number	Document Date	Document Type	Document Remarks
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**Remarks**

See continuation.

<b>Payment Amount</b> \$124.55	<b>Payment Method</b> Billed	<b>704(d) Sample</b> No	<b>702(b) Portion</b> No	<b>Collector's Name</b> April R Bowen
<b>Name of Signer</b> April R Bowen	<b>Date &amp; Time of Signature</b> 02/19/2008 11:49 AM ET			<b>Meaning</b> Collector

Date: 03/01/2010

Page: 2 of 3

**Food and Drug Administration Office of Regulatory Affairs**

**Collection Report**

**For Sample Number: 453913**

This is an accurate reproduction of the original electronic record as of 03/01/2010.

**Continuation:**

**Product Label**

The sample bottle is labeled in part: "NDC 62794-145-10 DIGITEK (digoxin tablets, USP) 125 mcg (0.125 mg) 1000 TABLETS Rx only Each tablet contains: Digoxin, USP\*\*\*125 mcg (0.125 mg)\*\*\*Distributed by: BERTEK PHARMACEUTICALS INC. Sugar Land, TX 77478 USA Manufactured by: AMIDE PHARMACEUTICAL, INC. 101 East Main Street Little Falls, NJ 07424 USA Control No.:70737A1 Exp. Date: SEP 09\*\*\*".

**How Prepared**

The sample bottle is identified as: "453913 02/15/08 ARB", placed in a whirl-pak bag identified as "453913 02/15/08 ARB", and officially sealed "453913 02/15/08 April R. Bowen". FDA form 525 was attached to the bag. The sample was placed in a box to be delivered to NRL via FedEx on 02/19/08.

**Remarks**

The sample was collected on 02/15/08, officially sealed, and kept under the supervision of Investigator April R. Bowen, under lock and key, under ambient conditions until prepared for shipping on 02/19/08.

**Food and Drug Administration Office of Regulatory Affairs****Summary Report****For Sample Number: 453913****TD Sample Number:****Import Sample Number**

This is an accurate reproduction of the original electronic record as of 06/10/2008

**Sample Class:** Normal Everyday Sample      **Sample Origin:** Domestic      **Sample Basis:** Surveillance  
**Sample Type:** Official      **Collecting District:** ATL-DO  
**Home District:**      **Orig C/R and Records To:** NWJ-DO      **Collection PACs:** 56008A  
**Product Name:** Digoxin (Cardiotonic); Human - Rx/Single Ingredient; Prompt Release Tablets  
**Product Description:** Digoxin Tablets, USP packed in a white plastic bottle w/white screw-on top, NDC 62794-145-10.  
**Collection Reason:** Sample collected as part of the FY 2008 Low Cost Generic Drug Sample Survey (CP 7356.008) FACTS Assignment #896749 ORA concurrence #2008101702.

<b>Lab:</b> NRL	<b>Split Num</b> 0	<b>Date Received:</b> 02/20/2008	<b>Date Out of Lab:</b> 06/10/2008
<b>District Conclusion:</b>		<b>District Conclusion Made By:</b>	<b>District</b>
<b>Disposition Reason:</b>		<b>Disposition Authorized By:</b>	<b>Disposition Authorized Date</b>

<b>Performing Org</b>	<b>PAC</b>	<b>LID</b>	<b>PAF</b>	<b>Compliance No</b>	<b>Lab Class-Description</b>	<b>Laboratory Status</b>
NRL-DCB-G	56008A		DRT		I - In Compliance	Completed

**Lab Conclusion**

The sample meets USP specifications for Identification, Content Uniformity and Dissolution.

**Lab Conclusion Date****Lab Conclusion Made By**

06/10/2008

Mathew, Samuel K

Date: 06/10/2008

Page: 1 of 1

FLAG Original

<b>ANALYST WORKSHEET</b>		1. PRODUCT DIGITEK (digoxin tablets, USP) 125 mcg (0.125 mg)		2. SAMPLE NUMBER 453913	
3. SEALS <input type="checkbox"/> NONE <input checked="" type="checkbox"/> INTACT <input type="checkbox"/> BROKEN		4. DATE REC'D 2/27/08	5. RECEIVED FROM Howard Lynch		6. DISTRICT OF LABORATORY NRL
7. DESCRIPTION OF SAMPLE  One clear, plastic bag officially sealed, "453913 02/15/08 April R. Bowen Investigator", containing one product bottle identified "453913 02/15/08 ARB". An FDA 525 is attached to the sample.					
8.  NET CON- TENTS	<input type="checkbox"/> NOT APPLICABLE <input checked="" type="checkbox"/> NOT DETERMINED _____ UNITS EXAMINED		DECLARE/UNIT AMOUNT FOUND % OF DECLARED		9.  LABEL- ING  _____ ORIGINAL(S) SUBMITTED <u>1</u> COPIES SUBMITTED <input type="checkbox"/> NONE
10. SUMMARY OF ANALYSIS  Container: Round, opaque, white, plastic bottle with a similar, screw-on cap. Safety-seal beneath cap is intact. Bottle is approximately 5.5 cm. in diameter and 11 cm. in height.  Labeling: Commercially-printed, rectangular, paper, stick-on label. Commercially-printed product insert is inside bottle.  Code: " Control No.: 70737A1 " and " Exp. Date: SEP 09 " printed on the bottle label.  Product: Round, flat and bevel, solid, light-yellow tablet. Tablet is unmarked and unscored on one side. Opposite side is 1/2-scored with markings "B" and "145". Tablet is approximately 6.5 mm in diameter.  Analysis: Identification, Dissolution, and Content Uniformity.  Method: USP 30 - NF 25, p. 1943.  Results: See general continuation sheet page 2.					
11. RESERVE SAMPLE  Original plastic bag containing one open product bottle. Bag is officially sealed " 453913 6/10/08 Valentino Fiorella Analyst". Bottle is additionally identified "VF 2/27/08" and contains approximately <u>988</u> tablets by weight. Sample returned to the sample custodian.					
12 a. ANALYST SIGNATURE (Broke Seal <input checked="" type="checkbox"/> ) <i>Valentino Fiorella</i>			13.  WORK- SHEET CHECK		a. BY <i>S. Mathew</i>
b.					b. DATE <i>6/10/08</i>
c.			14. DATE REPORTED <i>6/10/08</i>		

FORM FDA 431 (5/84)

PREVIOUS EDITION IS OBSOLETE

PAGE 1 OF 12 PAGES

ATTACHMENTS : A ( pp. 1 - 20 ), B

GENERAL CONTINUATION SHEET	PRODUCT Digoxin Tablets (0.125 mg)	SAMPLE NO. 453913
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**RESULTS:**

**Identification**

The retention time of the major peak in the chromatogram of the sample preparation corresponds to that in the chromatogram of the standard preparation. Complies

**Content Uniformity**

(See computer printout pages 6 - 7 for complete results)

Range: 95.4 % to 100.1 %; Average (X): 97.1 %;

RSD: 1.5 %; s: 1.43

Acceptance Value (AV) = 4.8 %

(Limit: AV ≤ 15.0 % unless otherwise specified in the individual monograph)

**Dissolution**

(See least squares line fitting pages 11 - 12 for complete results)

Range: 96.0 % to 109.7 %; Avg.: 101.9 %

(Limit: Each unit is NLT Q+5% (Q=80%) for 6 units tested (Stage 1))

ANALYST(S) <i>Valentino Furell</i>	ANALYST NO. 113	PAGE 2 OF 12 PAGES
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GENERAL CONTINUATION SHEET	PRODUCT Digoxin Tablets (0.125 mg)	SAMPLE NO. 453913
ANALYST(S) <i>Valentino Fiorelli</i>	ANALYST NO. 113	PAGE 3 OF 12 PAGES



GENERAL CONTINUATION SHEET	PRODUCT Digoxin Tablets (0.125 mg)	SAMPLE NO. 453913
ANALYST(S) <i>Valentino Fiorillo</i>	ANALYST NO. 113	PAGE 4 OF 12 PAGES

General Continuation Sheet	Product: Digoxin Tablets (0.125 mg)	Sample No. 453913
<b>Statistical Analysis of Data:</b> Standard Solution 1 (CCV) 03/03/2008		
Relative STD Deviation	0.23 %	
Standard Deviation	1566.69471	
Average (mean)	678866.6	
Number of entries	5	
Range	677216 To 681220	
Data Entered:		
677721 ✓		
678819 ✓		
679357 ✓		
681220 ✓		
677216 ✓		
Analyst(s) <i>Valentino Fiorello</i>	Analyst No. 113	Page 5 of 12 Pages

General Continuation Sheet	Product: Digoxin Tablets (0.125 mg)	Sample No. 453913
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### Content Uniformity

No. of Units Examined	10
Standard Weight	2.424 mg.
Standard Dilution	200
Sample Dilution	10

Data Entered:

Unit #1	673009	STD #1	678867
Unit #2	678988	Blank	0
Unit #3	668085		
Unit #4	679994		
Unit #5	673742		
Unit #6	692885		
Unit #7	682775		
Unit #8	676772		
Unit #9	673296		
Unit #10	700860		

03/04/2008

CONTENT UNIFORMITY RESULTS:

	FOUND ( mg/tablet )	DECLARED	% of DECLARED
UNIT #1	0.120	0.125	96.1
UNIT #2	0.121	mg/tablet	97.0
UNIT #3	0.119		95.4
UNIT #4	0.121		97.1
UNIT #5	0.120		96.2
UNIT #6	0.124		99.0
UNIT #7	0.122		97.5
UNIT #8	0.121		96.7
UNIT #9	0.120		96.2
UNIT #10	0.125		100.1
<b>AVG.</b>	<b>0.121</b>		<b>97.1</b>

OFFICIAL LIMITS: 90.0 % TO 105.0 %

No. of Units Examined 10

**RANGE 95.4 % TO 100.1 % of Declared**

UNITS >=85 BUT <=115 % of Avg. Limit :

UNITS >=75 BUT <85 OR >115 BUT <=125 % of Avg. Limit :

UNITS <75 OR >125 % of Avg. Limit :

REL. STD. DEV. : 1.5 LIMIT <= 6.0%

10

0

0

mg/unit = (R\_spl \* std\_wt \* spl\_dil) / (R\_std \* std\_dil \* 1 unit)

Analyst(s) <i>Valentino Fiolella</i>	Analyst No. 113	Page 6 of 12 Pages
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General Continuation Sheet	Product: Digoxin Tablets (0.125 mg)	Sample No. 453913
<b>Statistical Analysis of Data:</b>		
Content Uniformity Standard Deviation		03/04/2008
Relative STD Deviation	1.47 %	
Standard Deviation	1.43	
Average (mean)	97.13	
Number of entries	10	
Range	95.4 To 100.1	
Data Entered:		
96.1'		
97'		
95.4'		
97.1'		
96.2'		
99'		
97.5'		
96.7'		
96.2'		
100.1'		
Analyst(s) <i>Valentino Finelli</i>	Analyst No. 113	Page 7 of 12 Pages

GENERAL CONTINUATION SHEET	PRODUCT Digoxin Tablets (0.125 mg)	SAMPLE NO. 453913
ANALYST(S) <i>Valentino Finelli</i>	ANALYST NO. 113	PAGE <i>8</i> OF <i>12</i> PAGES

GENERAL CONTINUATION SHEET	PRODUCT Digoxin Tablets (0.125 mg)	SAMPLE NO. 453913
ANALYST(S) <i>Valentino Finelli</i>	ANALYST NO 113	PAGE 9 OF 12 PAGES

FORM FDA 431a (5/84)

GENERAL CONTINUATION SHEET	PRODUCT Digoxin Tablets (0.125 mg)	SAMPLE NO. 453913
ANALYST(S) <i>Valentino Fiorella</i>	ANALYST NO. 113	PAGE 10 OF 12 PAGES

General Continuation  
Sheet

Product: Digoxin Tablets (0.125 mg)

Sample No.

453913

## Least Squares Line Fitting

06/05/2008

The Line Fitting used is  $Y = mX + b$ with  $m =$  0.021965and  $b =$  -0.0801

Correlation Coefficient = 0.99976175

Data Entered:

	X	Y	LSLF y	% Deviation
20% Std.	20	0.37	0.3592	3.007
40% Std.	40	0.774	0.7985	3.068
60% Std.	60	1.25	1.2378	0.986
80% Std.	80	1.683	1.6771	0.352
100% Std.	100	2.112	2.1164	0.208

Extrapolated Data:

	X	AVG	Y
Tablet 1-Test 1	112.55		2.392
Tablet 1-Test 2	106.81	109.68	2.266
Tablet 2-Test 1	98.66		2.087
Tablet 2-Test 2	99.07	98.87	2.096
Tablet 3-Test 1	102.26		2.166
Tablet 3-Test 2	105.35	103.81	2.234

Analyst(s)

*Valentino Lirio*Analyst No.  
113

Page 11 of 12 Pages



General Continuation Sheet	Product: Digoxin Tablets (0.125 mg)	Sample No. 453913																														
<div style="display: flex; justify-content: space-between; align-items: center;"><div>Least Squares Line Fitting</div><div>06/05/2008</div></div>																																
<p>The Line Fitting used is <math>Y = mX + b</math></p> <div style="display: flex; justify-content: space-between;"><div>with <math>m =</math></div><div>0.021965</div></div> <div style="display: flex; justify-content: space-between;"><div>and <math>b =</math></div><div>-0.0801</div></div> <div style="display: flex; justify-content: space-between;"><div>Correlation Coefficient =</div><div>0.99976175</div></div>																																
<p>Data Entered:</p> <table border="1" style="width:100%; border-collapse: collapse;"><thead><tr><th></th><th style="text-align: center;"><u>X</u></th><th style="text-align: center;"><u>Y</u></th><th style="text-align: center;"><u>LSLF y</u></th><th style="text-align: center;"><u>% Deviation</u></th></tr></thead><tbody><tr><td>20% Std.</td><td style="text-align: center;">20</td><td style="text-align: center;">0.37</td><td style="text-align: center;">0.3592</td><td style="text-align: center;">3.007</td></tr><tr><td>40% Std.</td><td style="text-align: center;">40</td><td style="text-align: center;">0.774</td><td style="text-align: center;">0.7985</td><td style="text-align: center;">3.068</td></tr><tr><td>60% Std.</td><td style="text-align: center;">60</td><td style="text-align: center;">1.25</td><td style="text-align: center;">1.2378</td><td style="text-align: center;">0.986</td></tr><tr><td>80% Std.</td><td style="text-align: center;">80</td><td style="text-align: center;">1.683</td><td style="text-align: center;">1.6771</td><td style="text-align: center;">0.352</td></tr><tr><td>100% Std.</td><td style="text-align: center;">100</td><td style="text-align: center;">2.112</td><td style="text-align: center;">2.1164</td><td style="text-align: center;">0.208</td></tr></tbody></table>				<u>X</u>	<u>Y</u>	<u>LSLF y</u>	<u>% Deviation</u>	20% Std.	20	0.37	0.3592	3.007	40% Std.	40	0.774	0.7985	3.068	60% Std.	60	1.25	1.2378	0.986	80% Std.	80	1.683	1.6771	0.352	100% Std.	100	2.112	2.1164	0.208
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Tablet 6-Test 2	98.07	95.95	2.074																													
Analyst(s) <i>Valentino Furell</i>	Analyst No. 113	Page 12 of 12 Pages																														

ATTACHMENT A - Page / of 20 pages

Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: Blank

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Blank-Rep2

Date: 03/03/2008 9:38:32 AM

Vial: 0

Injection Volume: 50 ul

Detector A

(218nm)

Pk #

Name

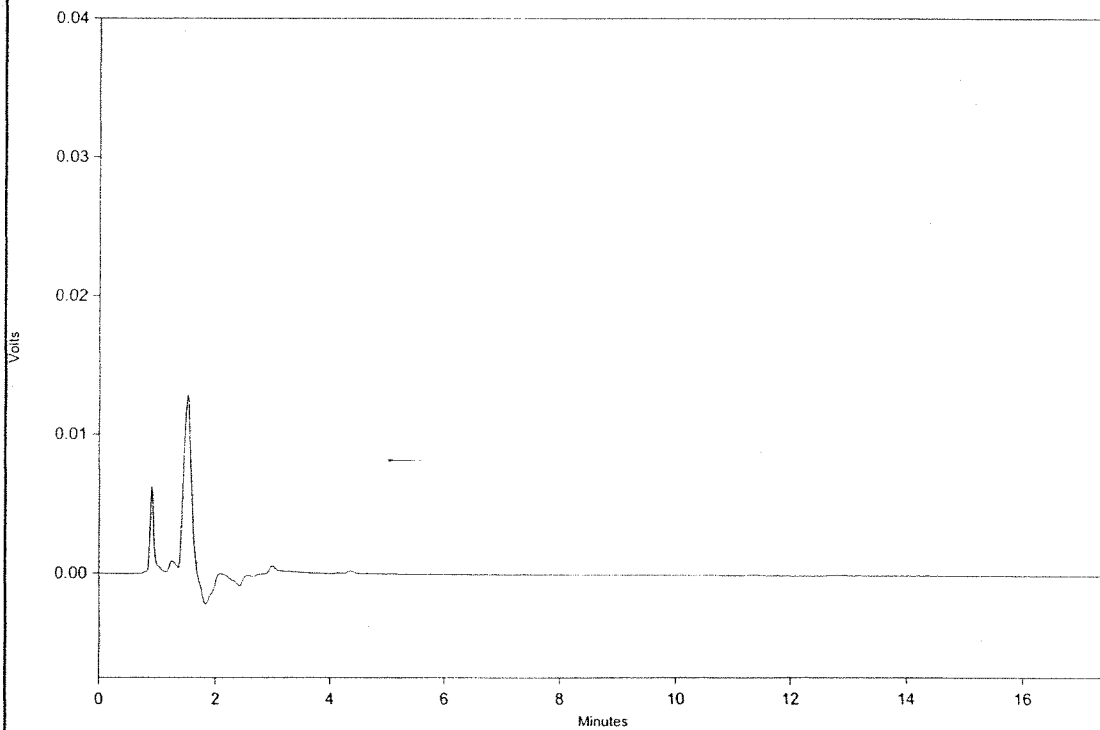
Retention  
Time

Area

Height

Asymmetry

Resolution

Theoretical  
plates

Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 2 of 20 pages

Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: System Suitability Solution

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\453913\SysSuitSoln

Date: 03/03/2008 9:57:33 AM

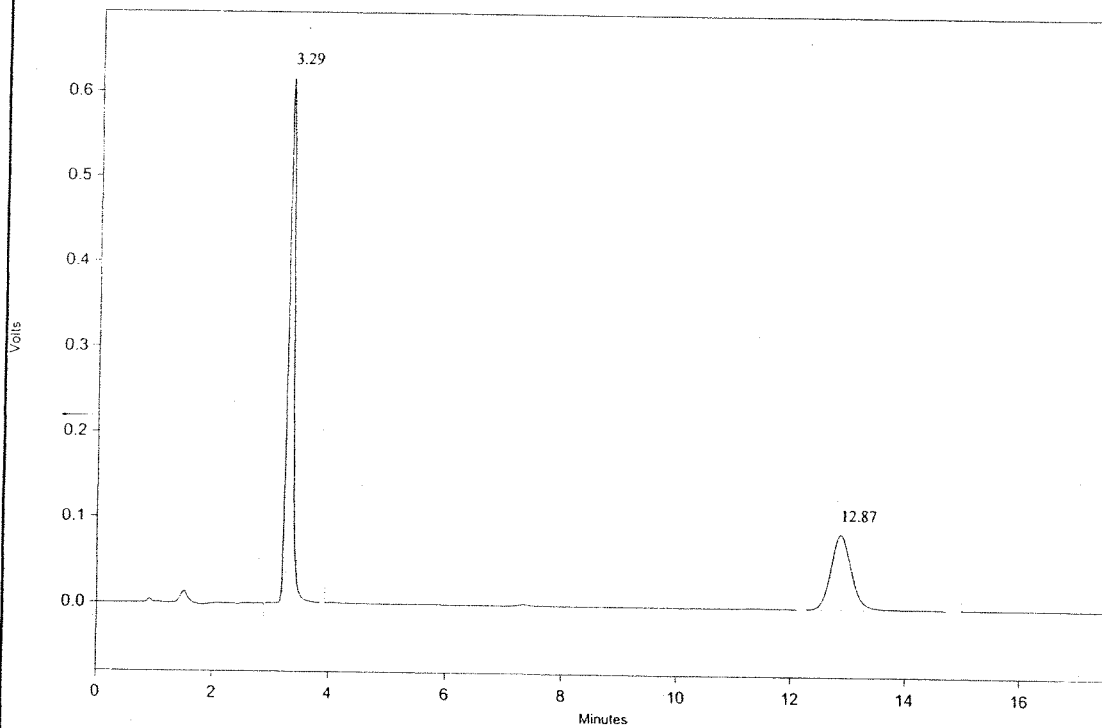
Vial: 1

Injection Volume: 50 ul

Detector A  
(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxigenin	3.29	4318725	616256	1.2	0.0	3452
2	Digoxin	12.87	2169893	87343	1.2	22.0	6364

Totals			6488618	703599			
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Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 3 of 20 pages

Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: Standard Solution 1 (CCV)

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Std.Soln-Rep1.

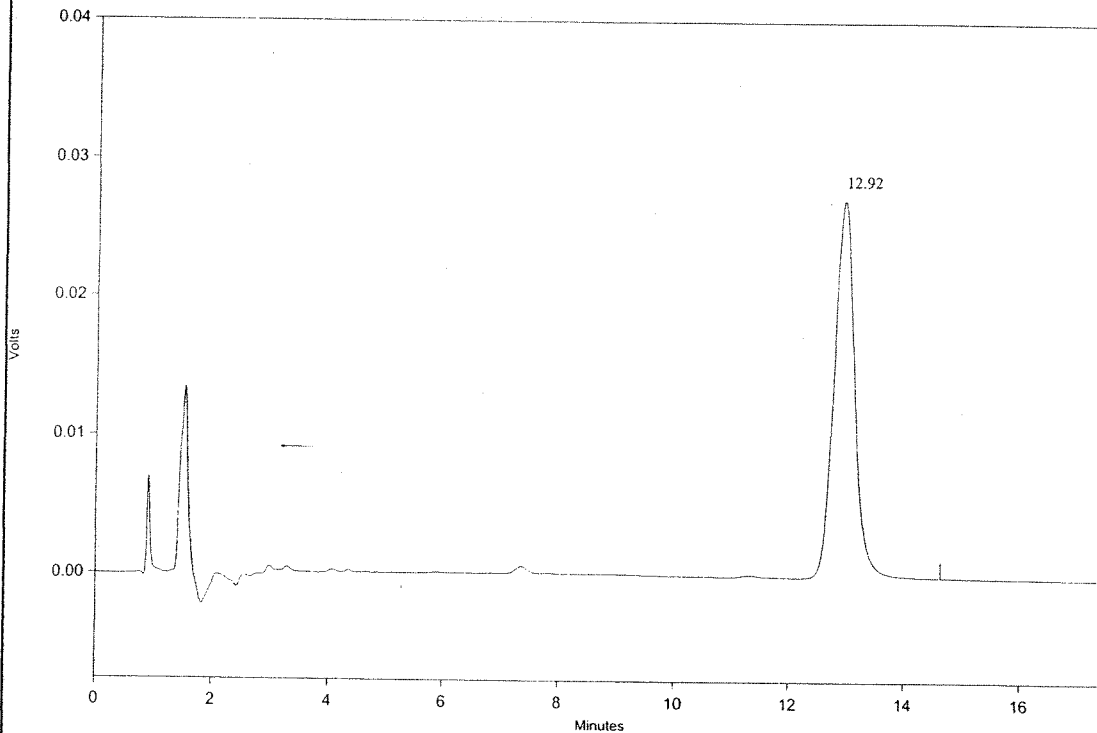
Date: 03/03/2008 10:16:33 AM

Vial: 2

Injection Volume: 50 ul

Detector A  
(218nm)

PK #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	12.92	677721	27189	1.2	0.0	6358
Totals			677721	27189			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 4 of 20 pages

Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: Standard Solution 1 (CCV)

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Std.Soln-Rep2.

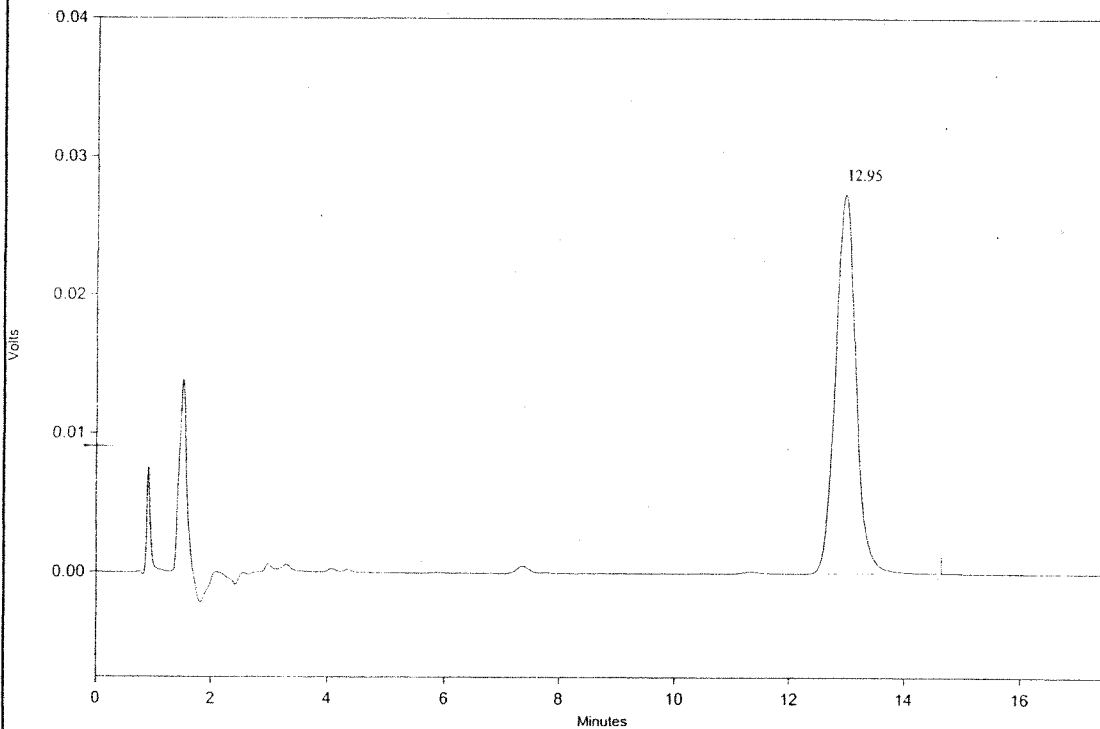
Date: 03/03/2008 10:35:32 AM

Vial: 2

Injection Volume: 50 ul

Detector A  
(218nm)

PK #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	12.95	678819	27370	1.1	0.0	6417
Totals			678819	27370			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 5 of 20 pages

Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: Standard Solution 1 (CCV)

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Std.Soln-Rep3.

Date: 03/03/2008 10:54:30 AM

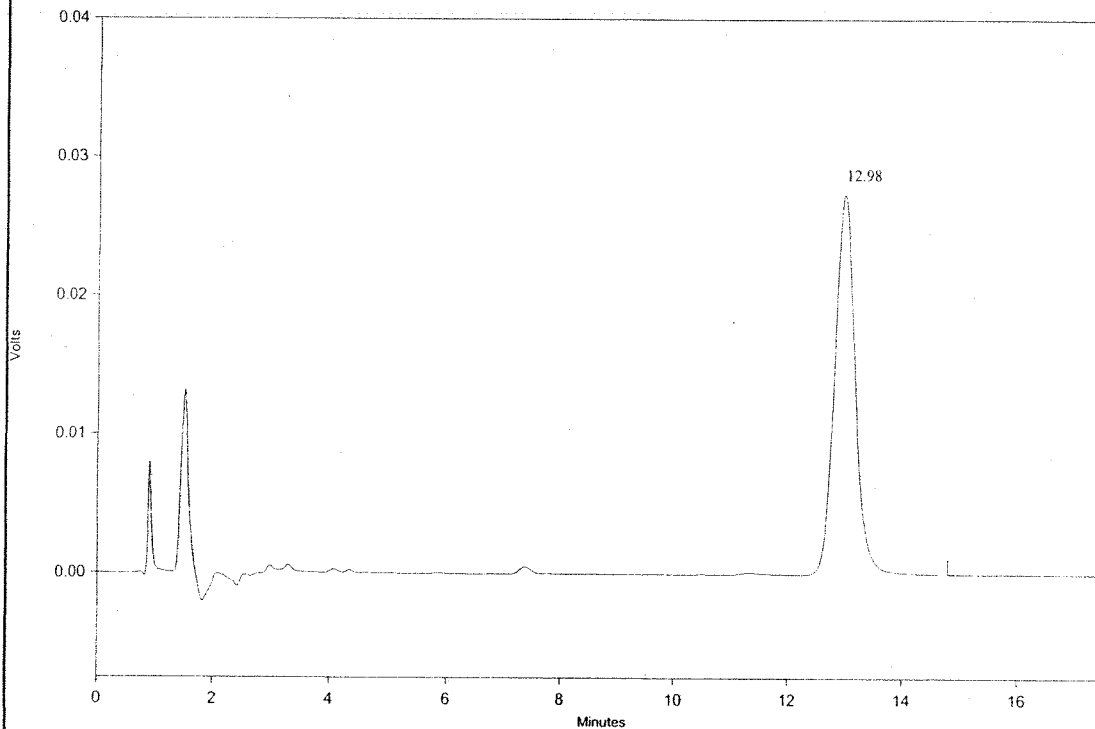
Vial: 2

Injection Volume: 50 ul

Detector A  
(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	12.98	679357	27392	1.1	0.0	6424

Totals			679357	27392			
--------	--	--	--------	-------	--	--	--



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 6 of 20 pages

Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: Standard Solution 1 (CCV)

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Std.Soln-Rep4.

Date: 03/03/2008 11:13:28 AM

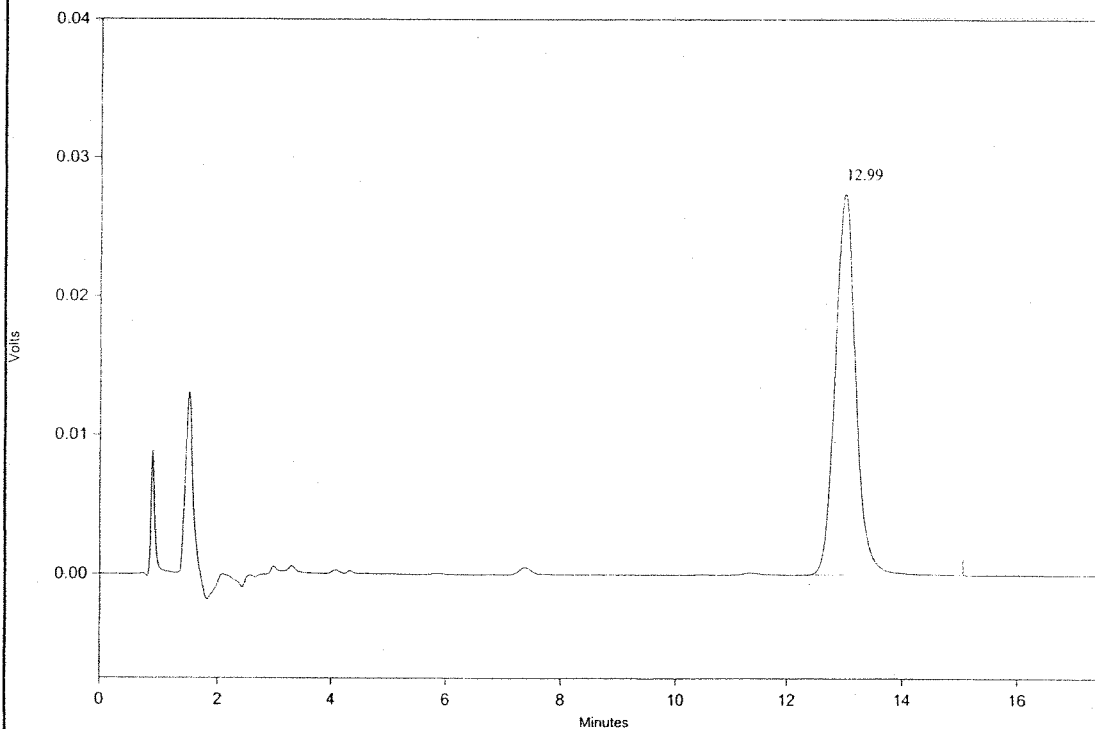
Vial: 2

Injection Volume: 50 ul

Detector A  
(218nm)

PK #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	12.99	681220	27435	1.1	0.0	6372

Totals			681220	27435			
--------	--	--	--------	-------	--	--	--



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 7 of 20 pages

Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: Standard Solution 1 (CCV)

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Std.Soln-Rep5.

Date: 03/03/2008 11:32:22 AM

Vial: 2

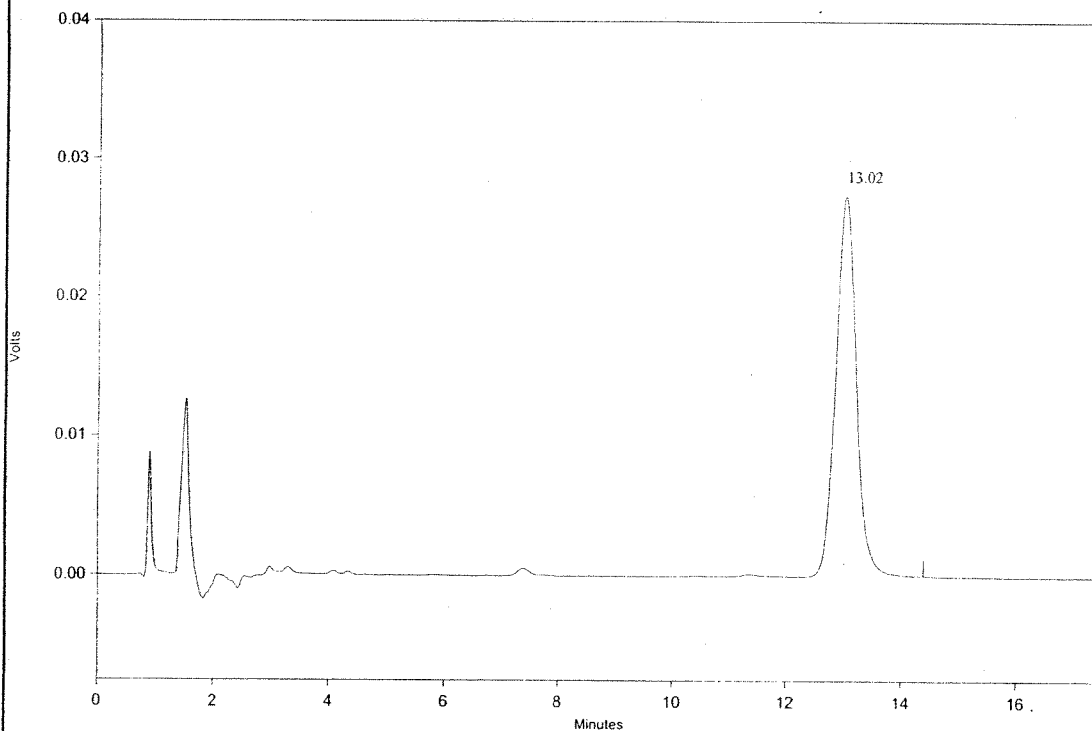
Injection Volume: 50 ul

Detector A

(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.02	677216	27387	1.1	0.0	6487

Totals			677216	27387			
--------	--	--	--------	-------	--	--	--



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C



ATTACHMENT A - Page 8 of 20 pages

Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: Standard Solution 2 (ICV)

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\453913\CheckStd.

Date: 03/03/2008 11:51:20 AM

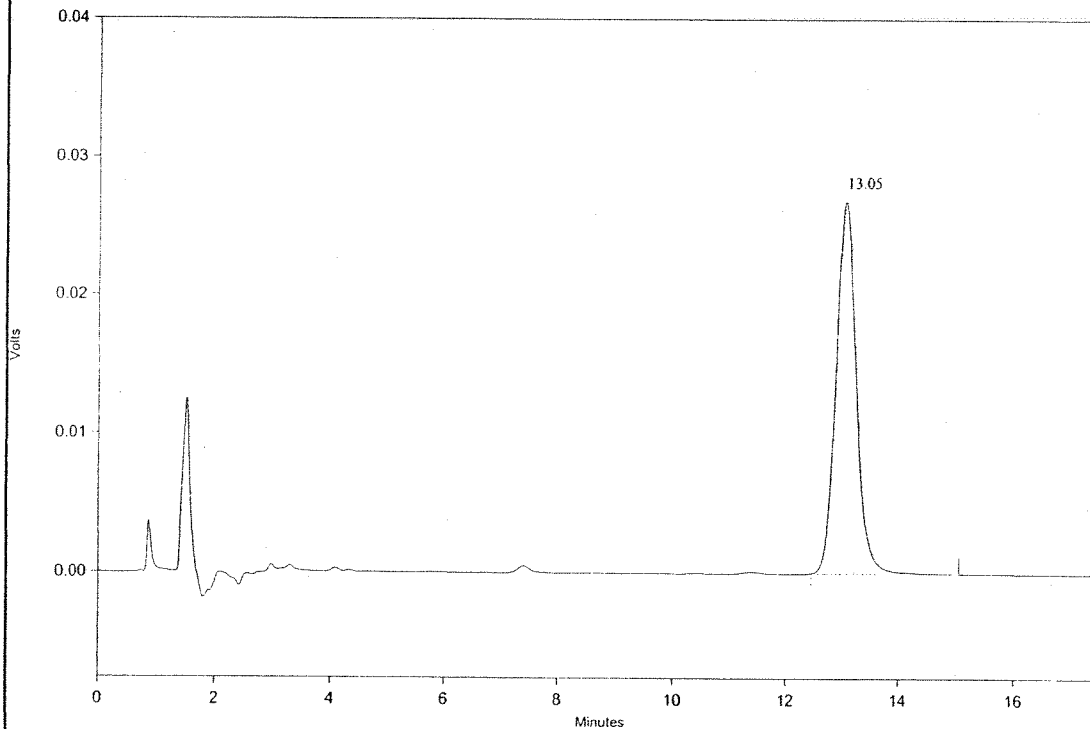
Vial: 3

Injection Volume: 50 ul

Detector A  
(218nm)

PK #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.05	671200	26815	1.1	0.0	6444

Totals			671200	26815			
--------	--	--	--------	-------	--	--	--



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 9 of 20 pages

Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: Tablet 1

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Tab1

Date: 03/03/2008 12:10:18 PM

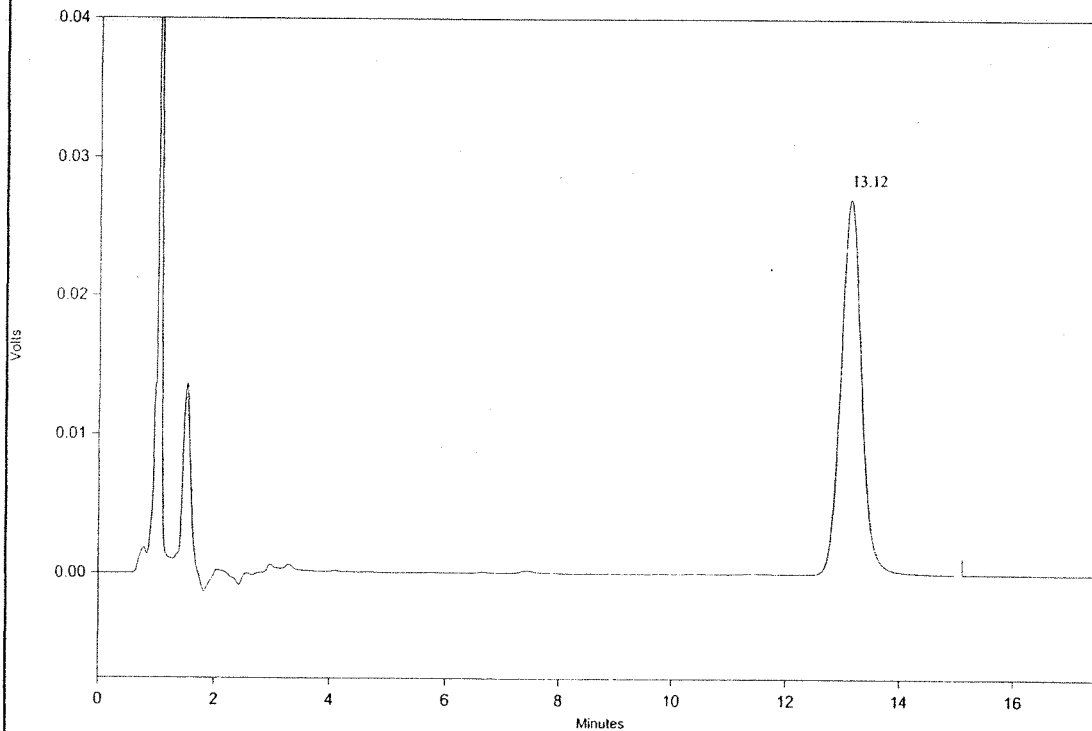
Vial: 4

Injection Volume: 50 ul

Detector A  
(218nm)

PK #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.12	673009	27049	1.1	0.0	6611

Totals			673009	27049			
--------	--	--	--------	-------	--	--	--



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 10 of 20 pages

Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: Tablet 2

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Tab2

Date: 03/03/2008 12:29:17 PM

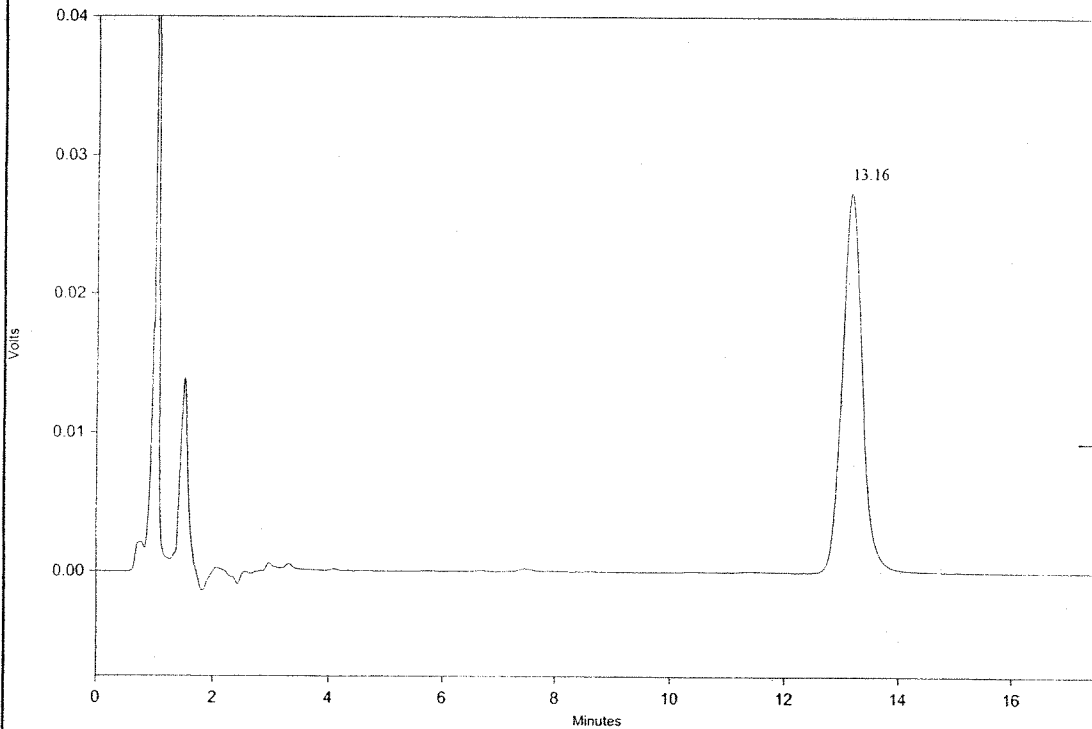
Vial: 5

Injection Volume: 50 ul

Detector A  
(218nm)

PK #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.16	678988	27390	1.1	0.0	6543

Totals			678988	27390			
--------	--	--	--------	-------	--	--	--



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 11 of 20 pages

Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: Tablet 3

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Tab3

Date: 03/03/2008 12:48:15 PM

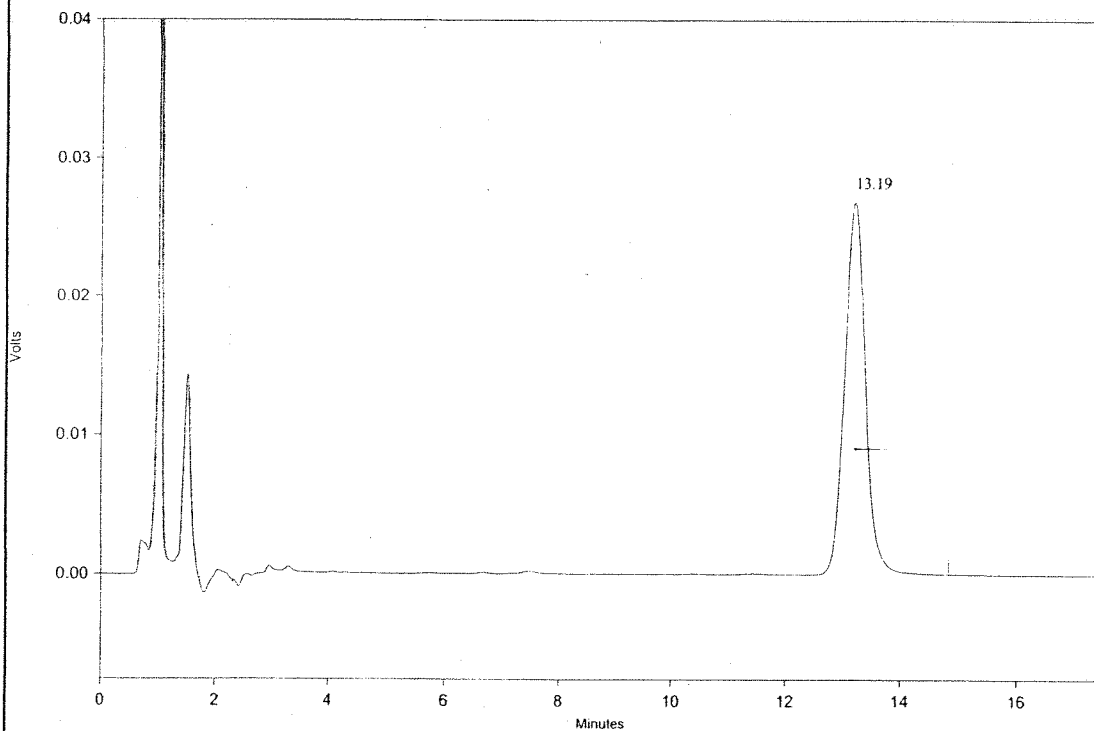
Vial: 6

Injection Volume: 50 ul

Detector A  
(218nm)

PK #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.19	668085	26856	1.1	0.0	6536

Totals			668085	26856			
--------	--	--	--------	-------	--	--	--



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 12 of 20 pages

Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: Tablet 4

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Tab4

Date: 03/03/2008 1:07:13 PM

Vial: 7

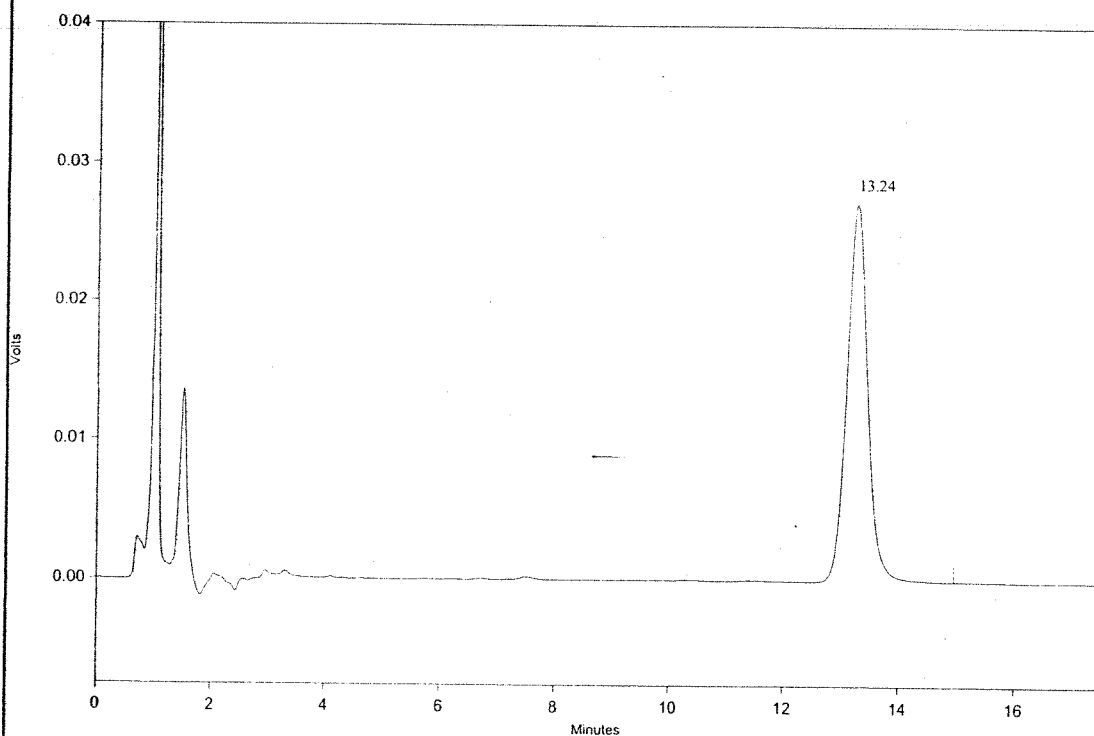
Injection Volume: 50 ul

Detector A

(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.24	679994	27235	1.1	0.0	6612

Totals			679994	27235			
--------	--	--	--------	-------	--	--	--



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 13 of 20 pages

Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: Tablet 5

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Tab5

Date: 03/03/2008 1:26:11 PM

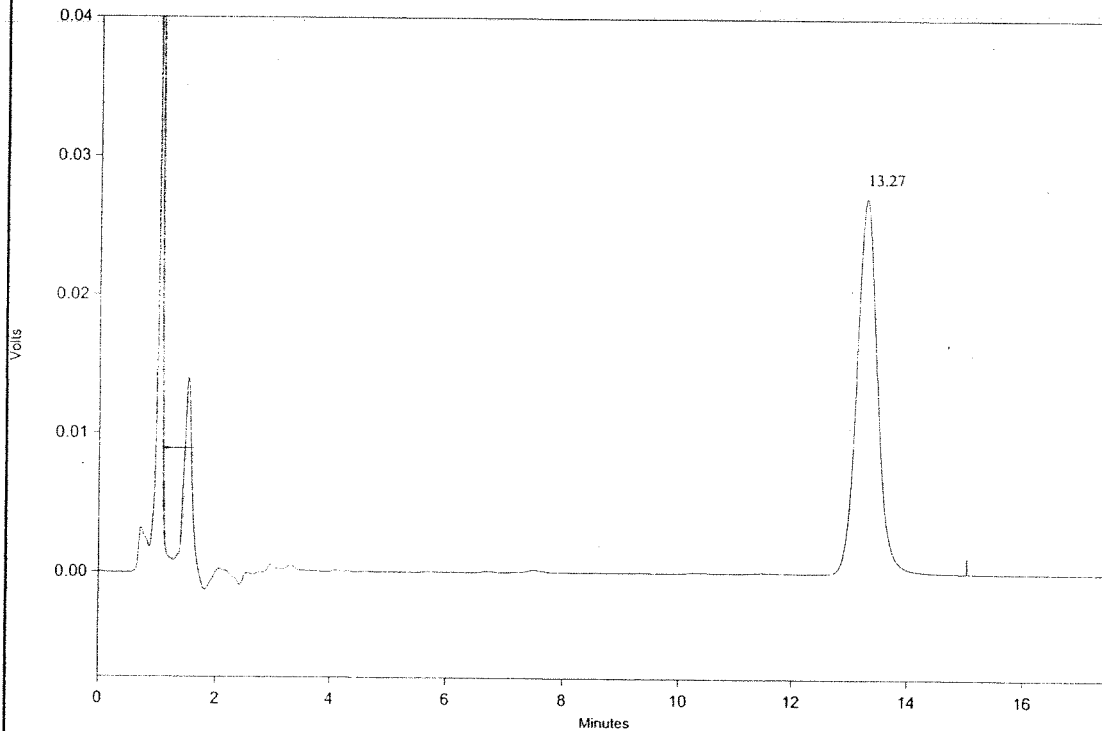
Vial: 8

Injection Volume: 50 ul

Detector A  
(218nm)

PK #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.27	673742	27036	1.1	0.0	6649

Totals			673742	27036			
--------	--	--	--------	-------	--	--	--



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 14 of 20 pages

Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: Standard Solution 1 (CCV)

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Std.Soln.6

Date: 03/03/2008 1:45:09 PM

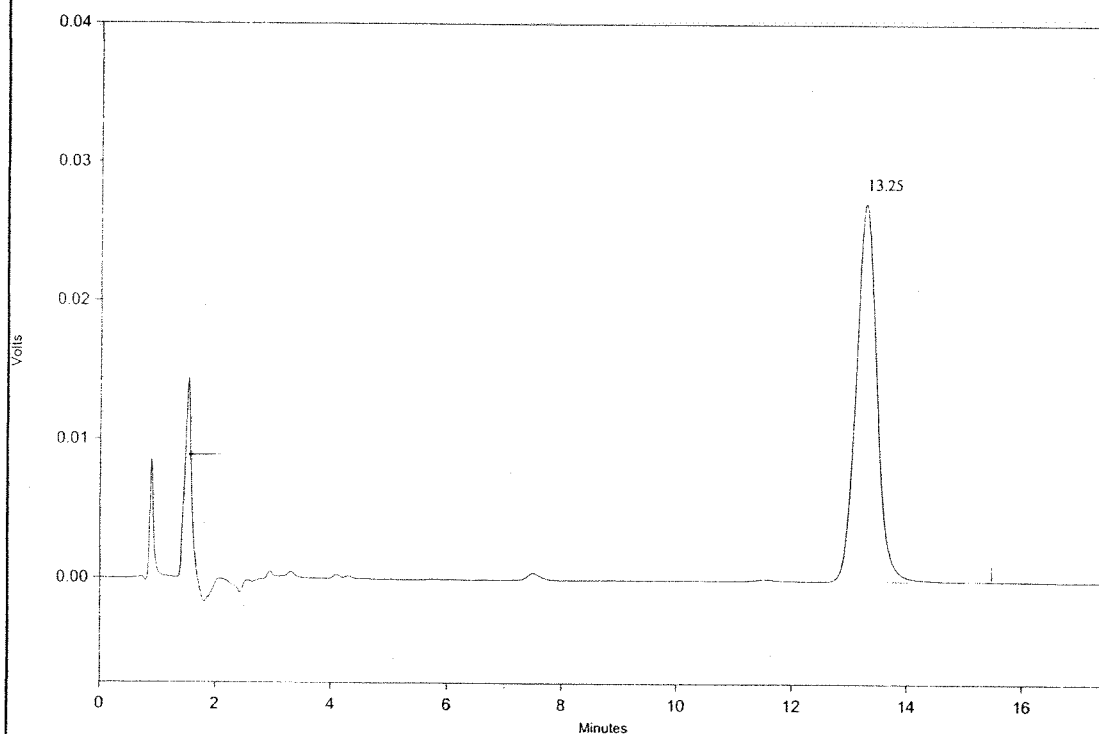
Vial: 2

Injection Volume: 50 ul

Detector A  
(218nm)

PK #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.25	678890	27219	1.1	0.0	6646

Totals			678890	27219			
--------	--	--	--------	-------	--	--	--



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 15 of 20 pages

Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: Tablet 6

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Tab6

Date: 03/03/2008 2:04:08 PM

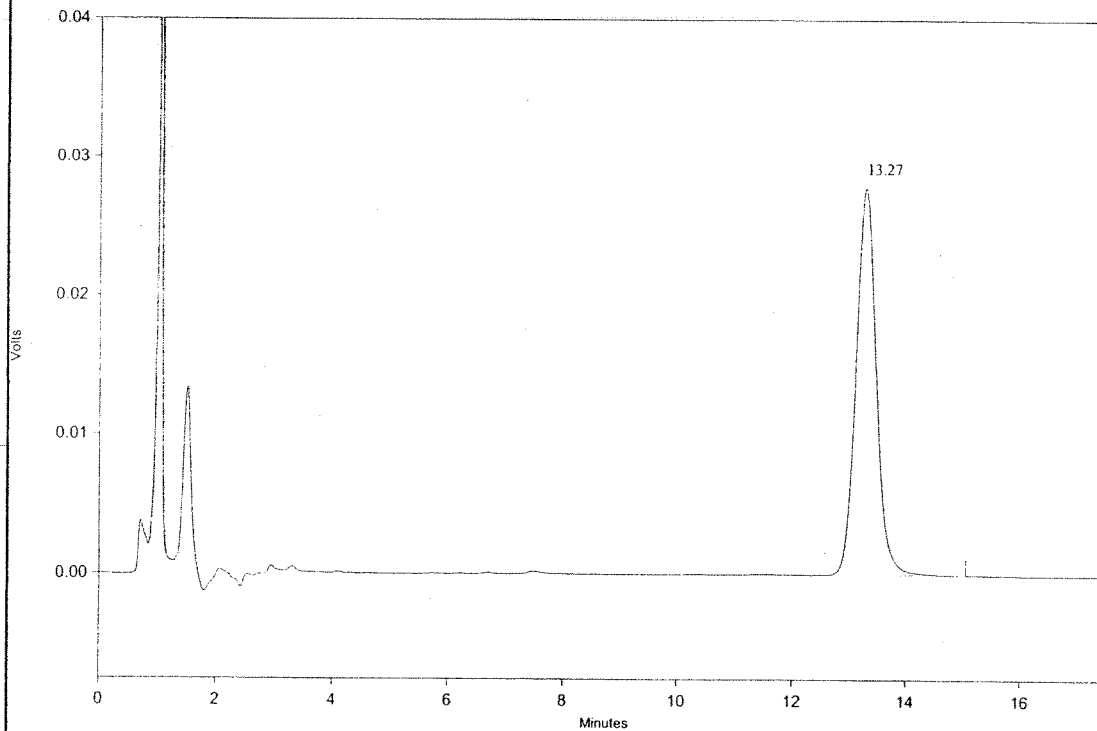
Vial: 9

Injection Volume: 50 ul

Detector A  
(218nm)

PK #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.27	692885	27805	1.1	0.0	6622

Totals			692885	27805			
--------	--	--	--------	-------	--	--	--



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C



ATTACHMENT A - Page 16 of 20 pages

Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: Tablet 7

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Tab7

Date: 03/03/2008 2:23:07 PM

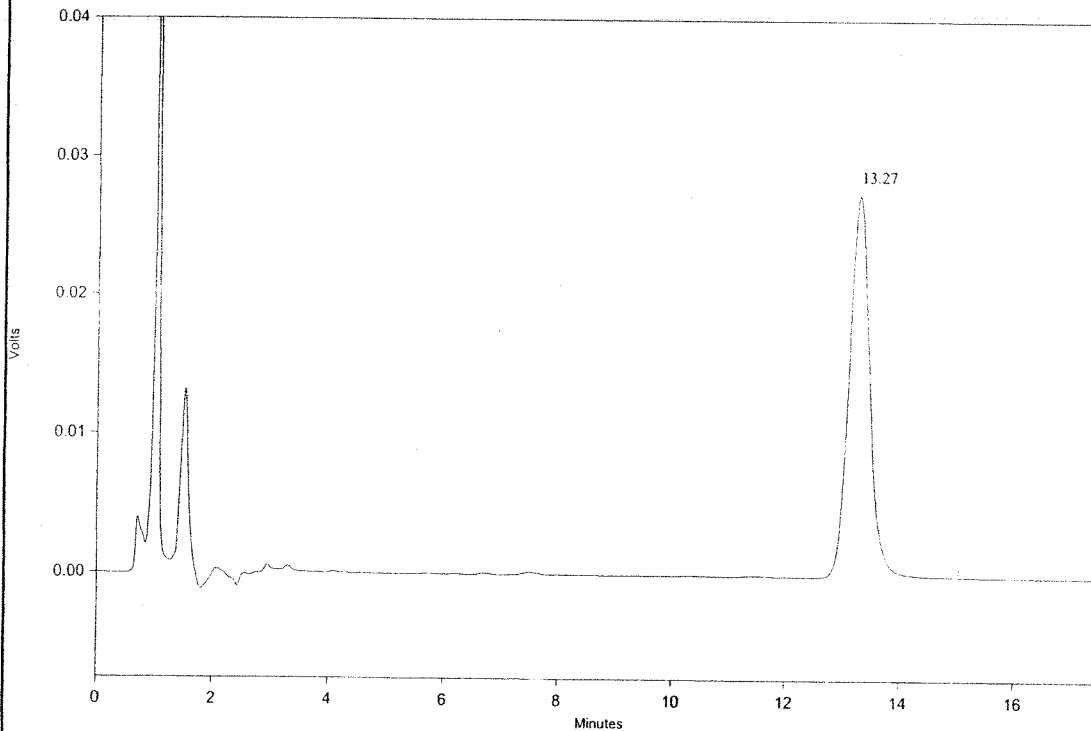
Vial: 10

Injection Volume: 50 ul

Detector A  
(218nm)

PK #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.27	682775	27431	1.1	0.0	6625

Totals			682775	27431			
--------	--	--	--------	-------	--	--	--



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 17 of 20 pages

Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: Tablet 8

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Tab8

Date: 03/03/2008 2:42:07 PM

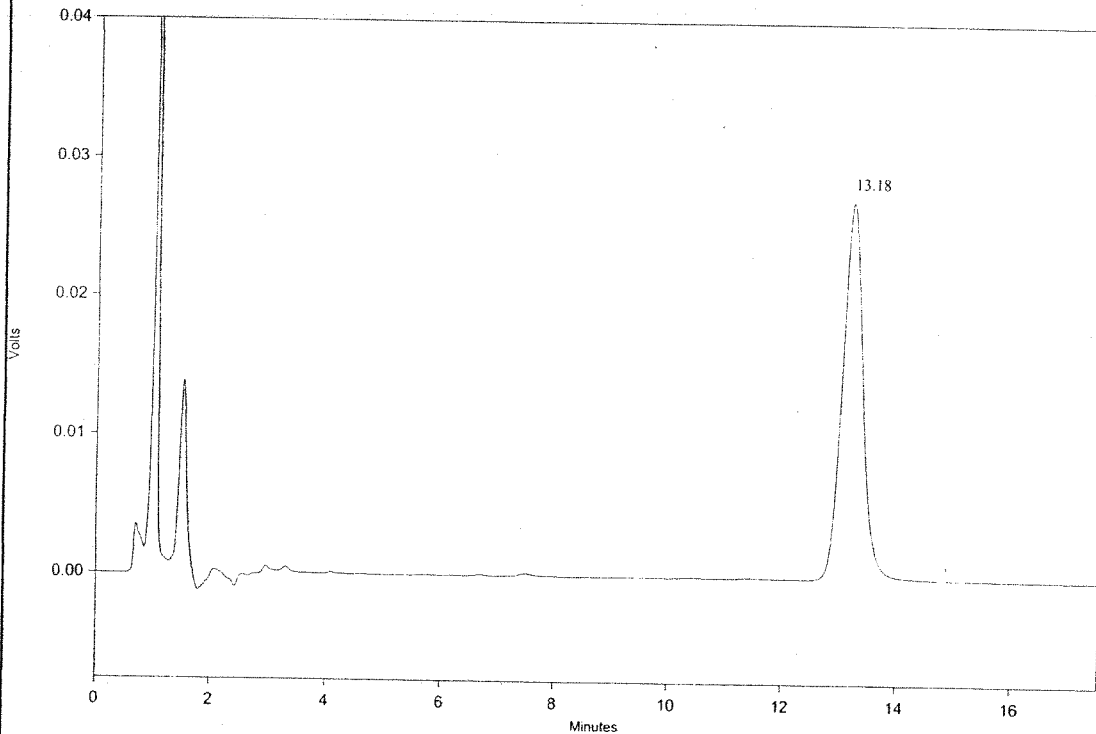
Vial: 11

Injection Volume: 50 ul

Detector A  
(218nm)

PK #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.18	676772	27151	1.1	0.0	6650

Totals			676772	27151			
--------	--	--	--------	-------	--	--	--



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 18 of 20 pages

Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: Tablet 9

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Tab9

Date: 03/03/2008 3:01:05 PM

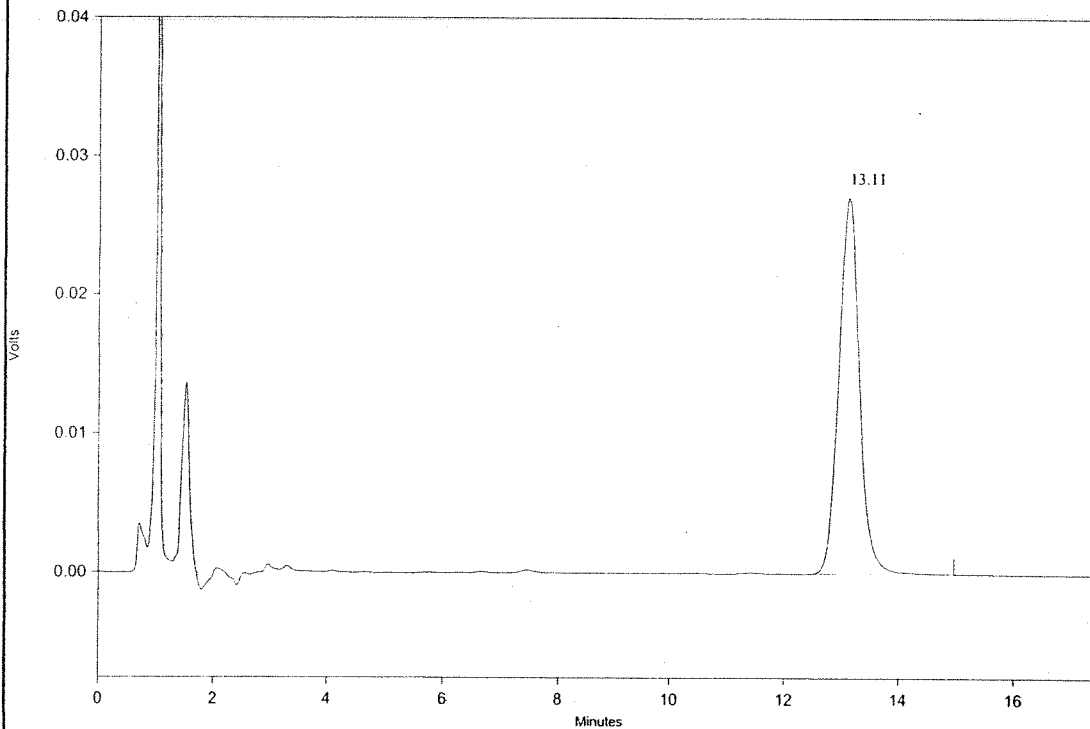
Vial: 12

Injection Volume: 50 ul

Detector A  
(218nm)

PK #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.11	673296	27081	1.1	0.0	6538

Totals			673296	27081			
--------	--	--	--------	-------	--	--	--



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 19 of 20 pages

Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: Tablet 10

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Tab10

Date: 03/03/2008 3:20:04 PM

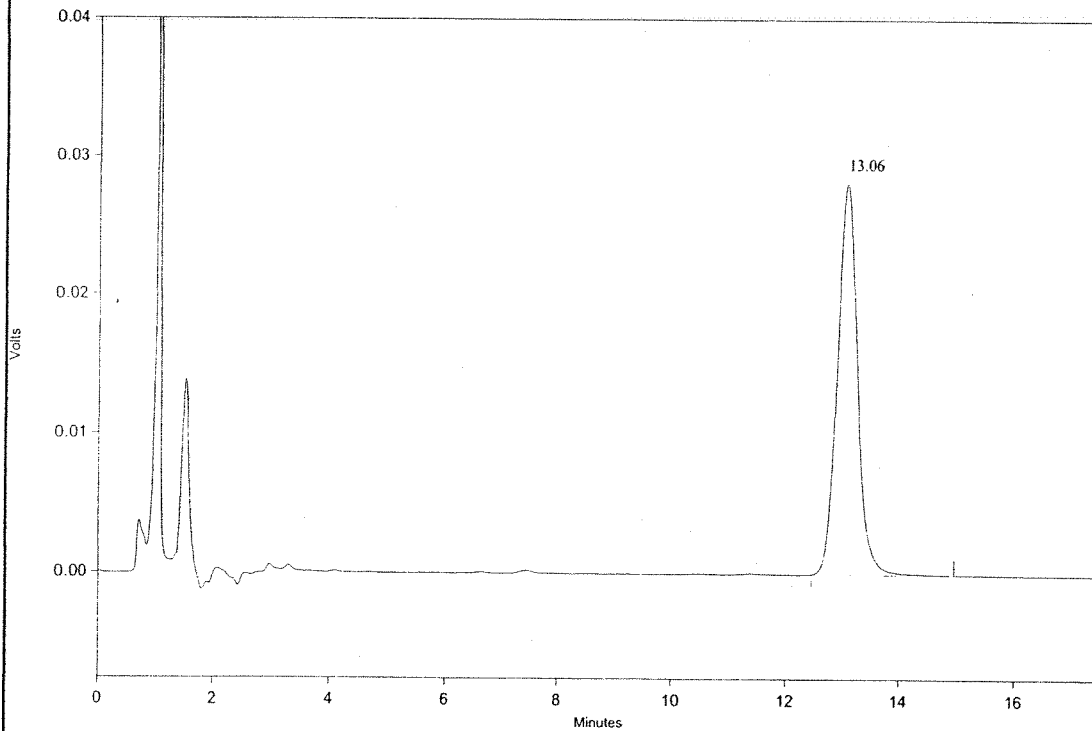
Vial: 13

Injection Volume: 50 ul

Detector A  
(218nm)

PK #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.06	700860	28158	1.1	0.0	6593

Totals			700860	28158			
--------	--	--	--------	-------	--	--	--



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 20 of 20 pages

Product: Digoxin Tablets (0.125 mg)

Spl.No. 453913

Name: Standard Solution 1 (CCV)

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\453913\Std.Soln.7

Date: 03/03/2008 3:38:59 PM

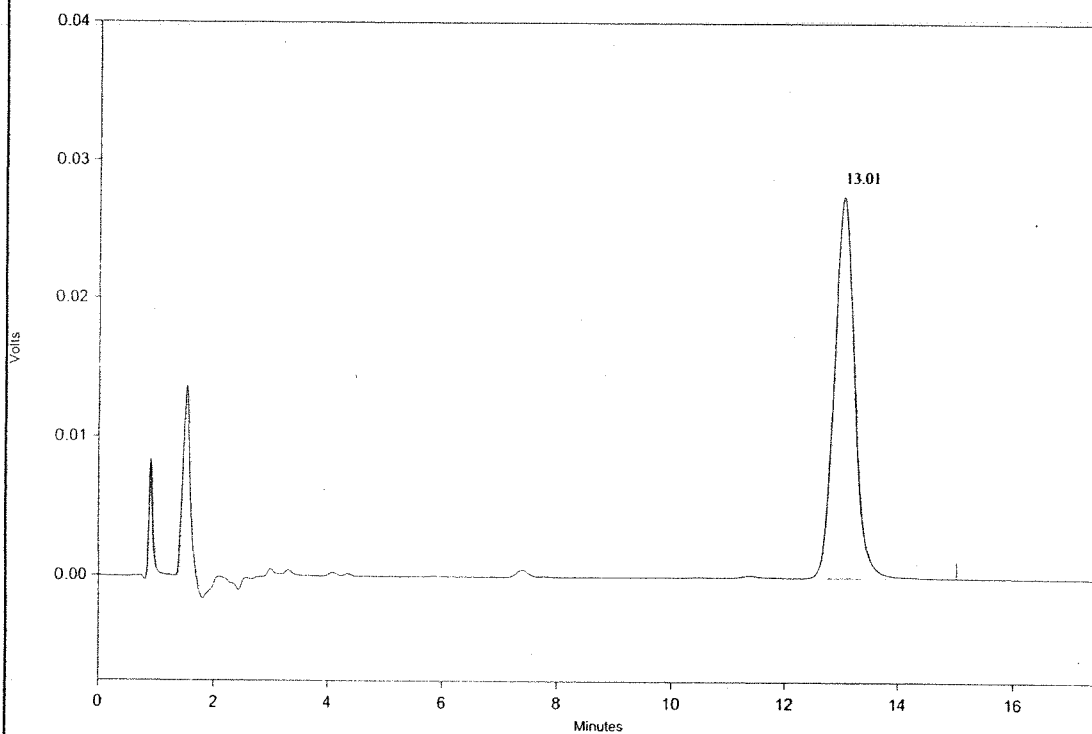
Vial: 2

Injection Volume: 50 ul

Detector A  
(218nm)

PK #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.01	680967	27510	1.1	0.0	6483

Totals			680967	27510			
--------	--	--	--------	-------	--	--	--



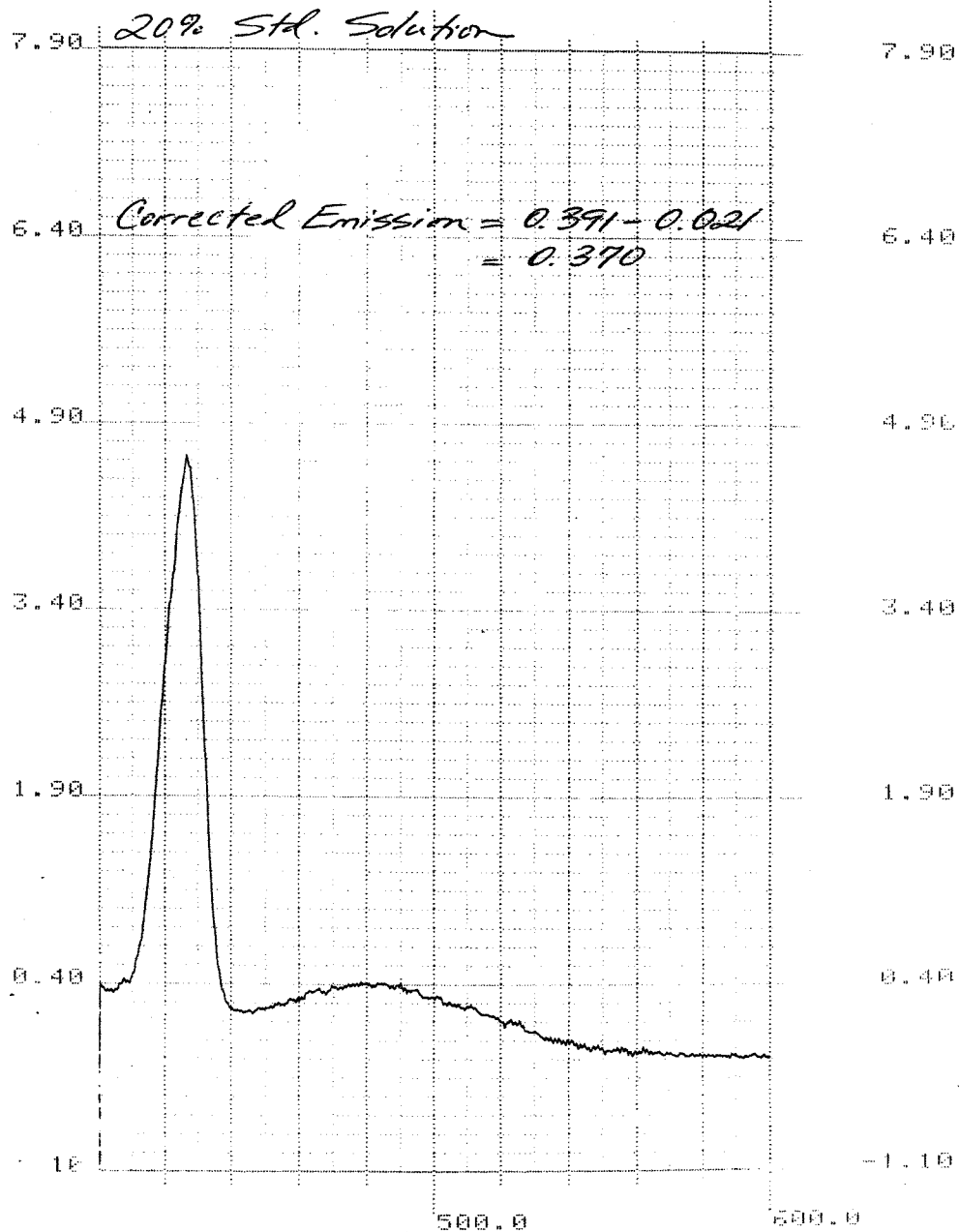
Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C



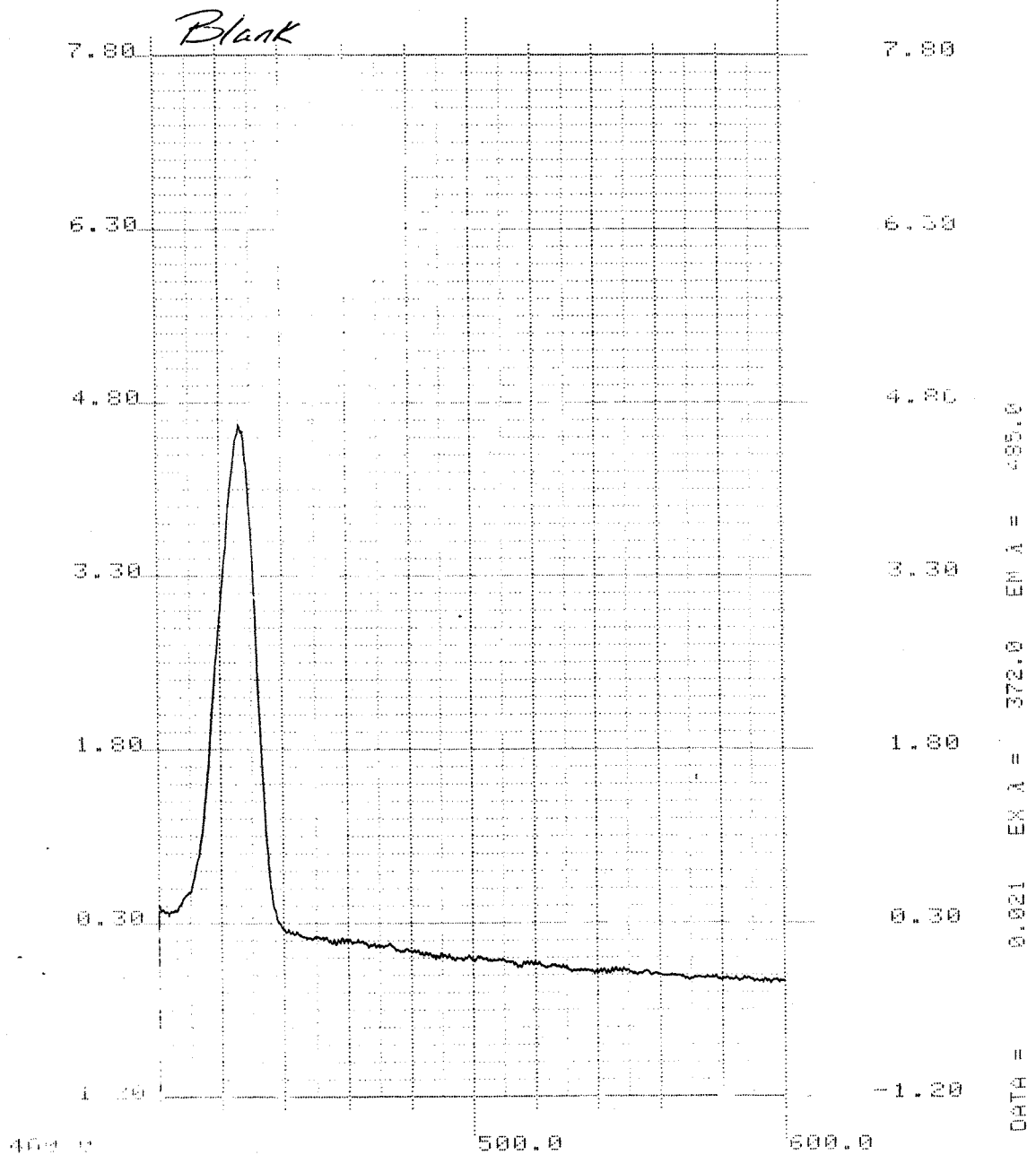
Attachment B

Digoxin Tablets (0.125 mg)

Spl.# 453913

6/4/08

Attachment B  
Digoxin Tablets (0.125mg)  
Spl. #453913  
6/4/08 VF

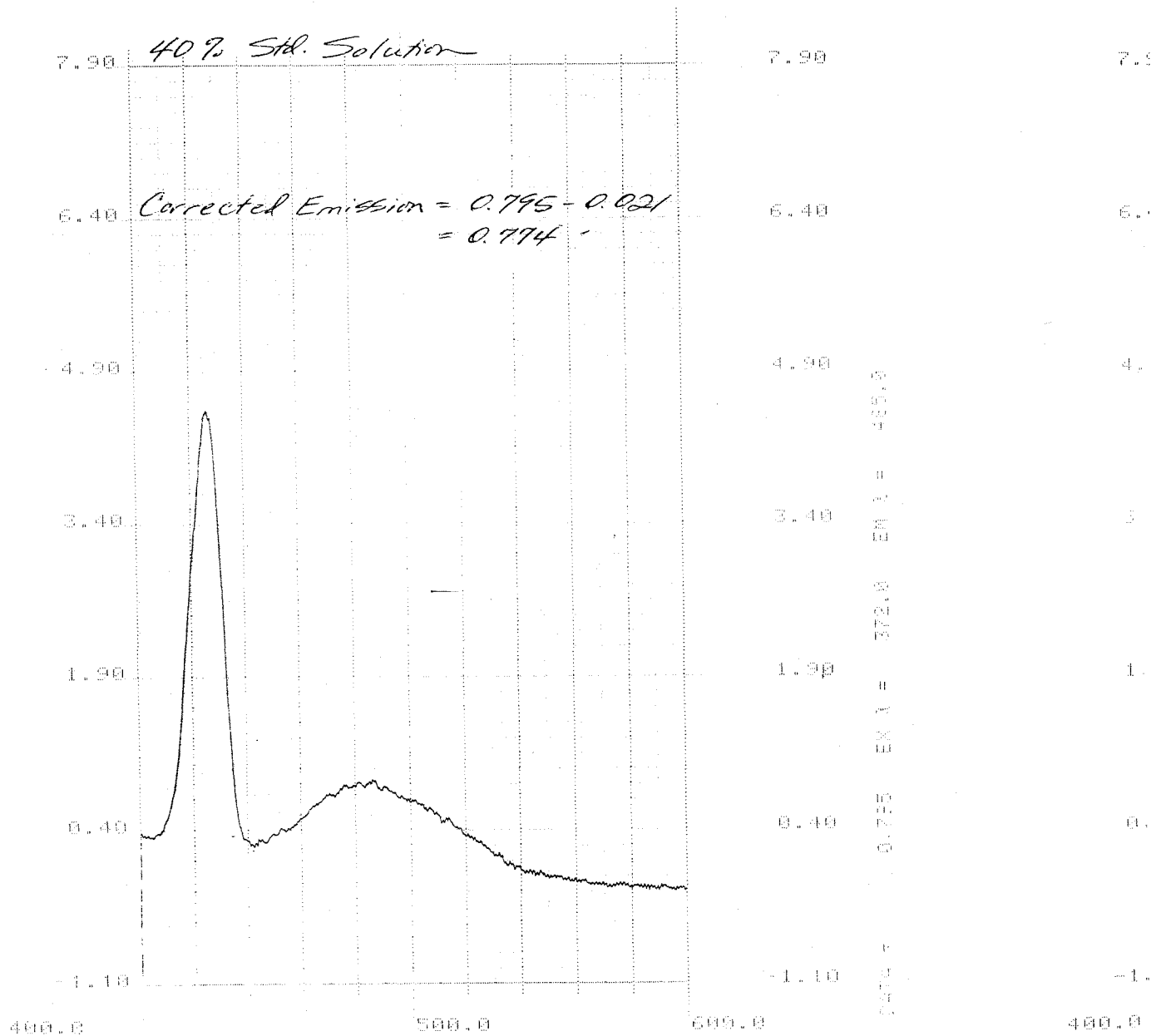


**Attachment B**

Digoxin Tablets (0.125 mg)

Spl.# 453913

6/4/08





60% Std. Solution

Corrected Emission =  $1.271 - 0.021$   
 $= 1.250$

7.90

6.40

4.90

3.40

1.90

0.40

-1.10

500.0

600.0

1.001 EX A = 572.0 EN A = 485.0

7.90

6.40

4.90

3.40

1.90

0.40

-1.10

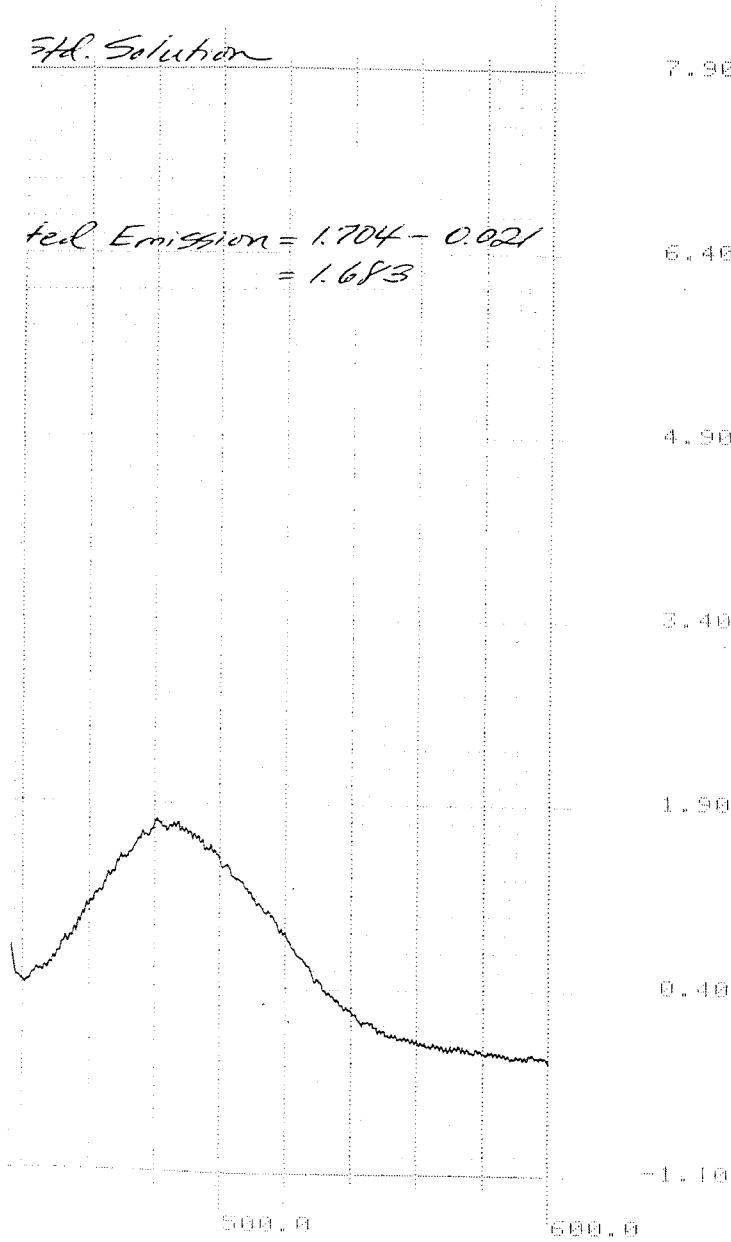
400.0

80

Corr.  
 $= 0$

*Std. Solution*

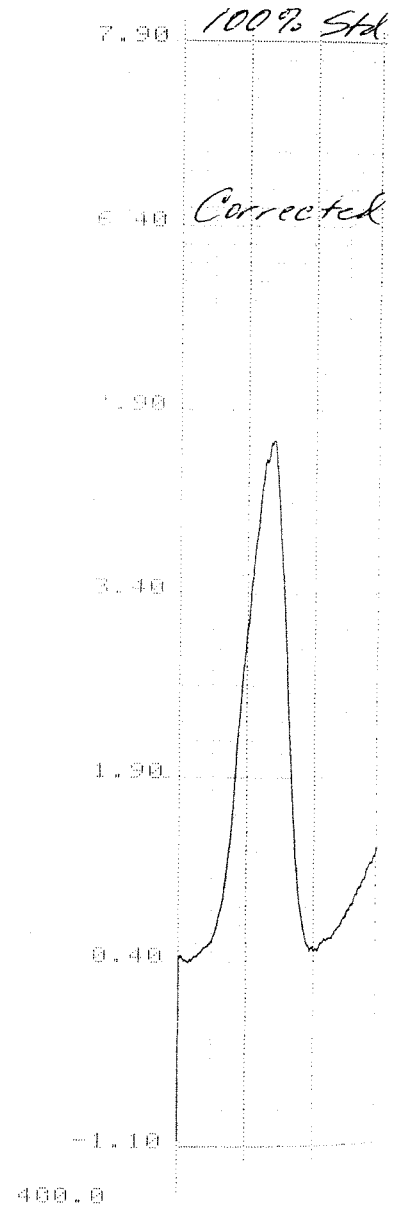
$$\text{Std. Emission} = 1.704 - 0.021 = 1.683$$



Wavelength = 1.704 EX A = 372.0 EM A = 485.0

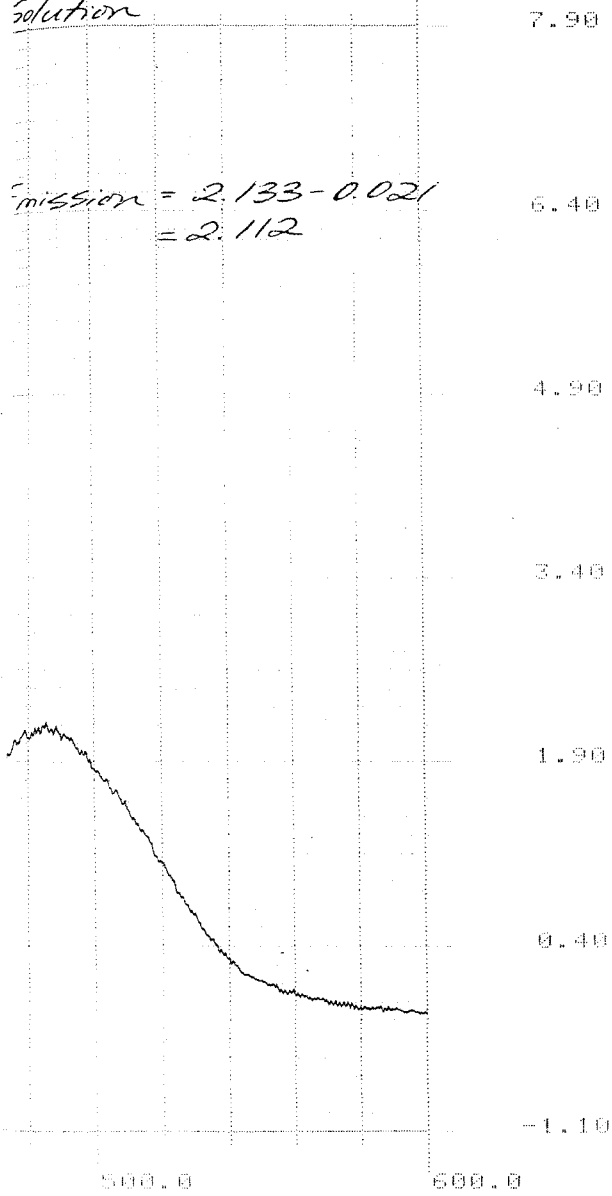
*100% Std*

*Corrected*



*Solution*

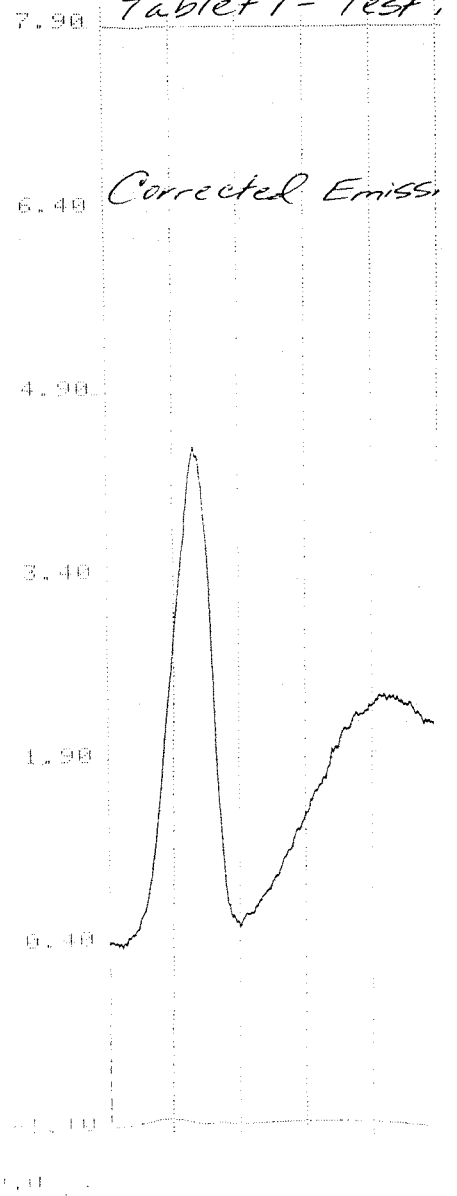
$$\begin{aligned} \text{Emission} &= 2.133 - 0.021 \\ &= 2.112 \end{aligned}$$



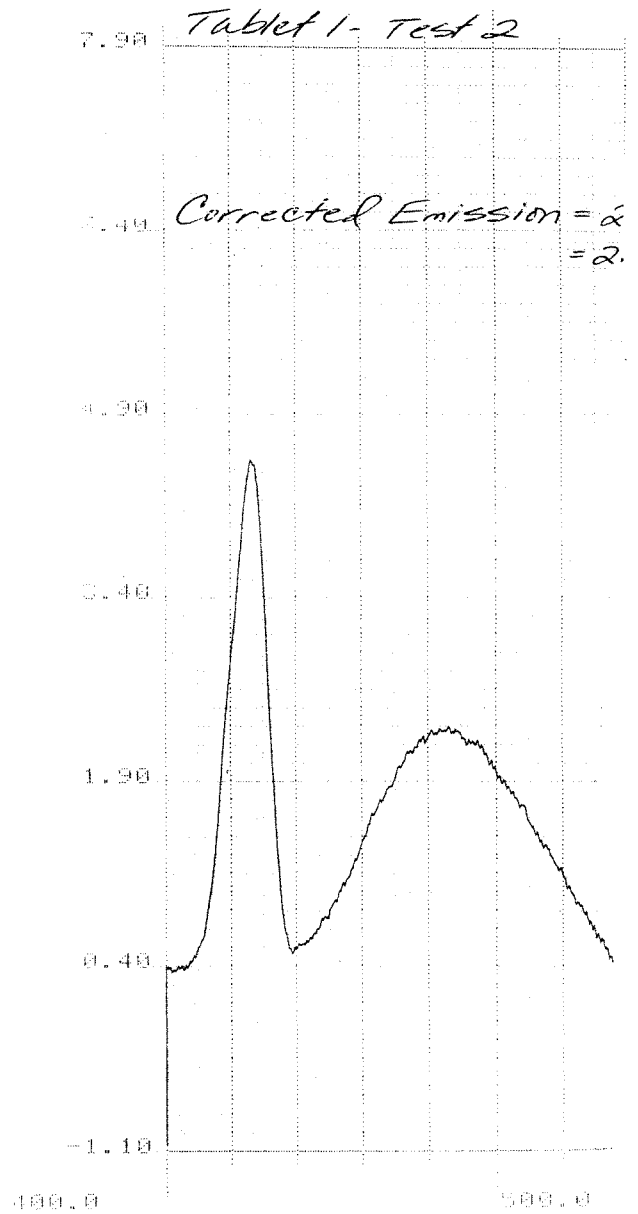
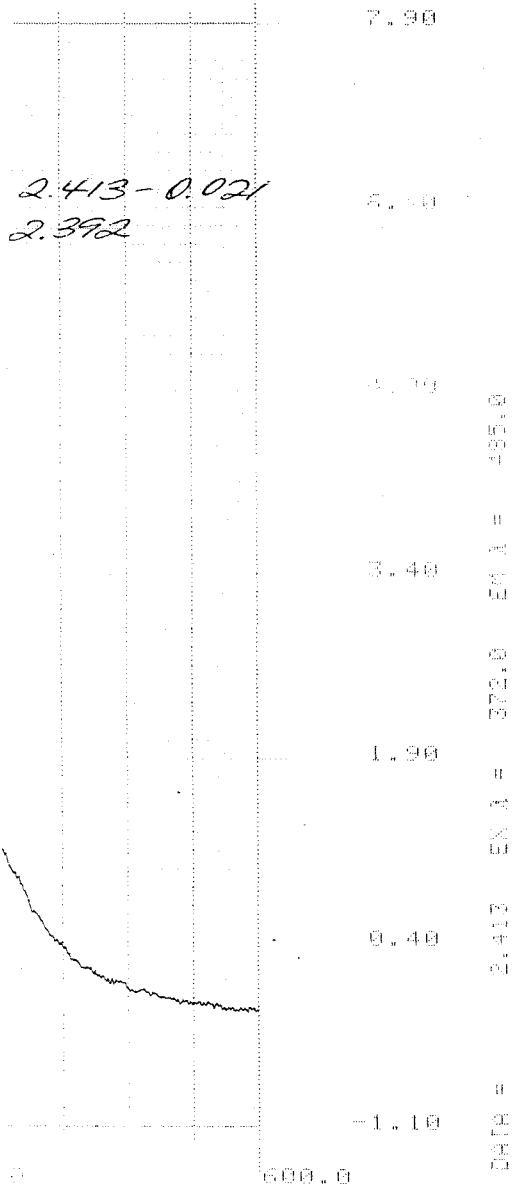
Wavelength (nm) = 500.0 510.0 520.0 530.0 540.0 550.0 560.0 570.0 580.0 590.0 600.0

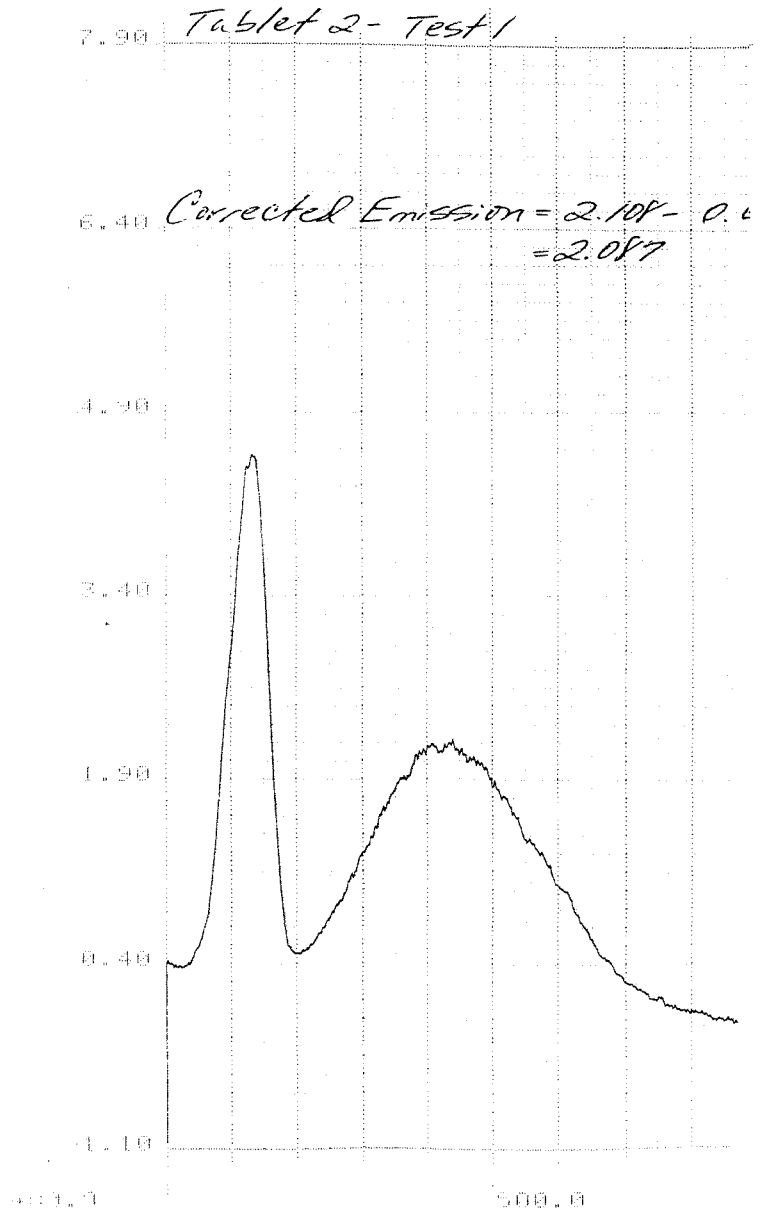
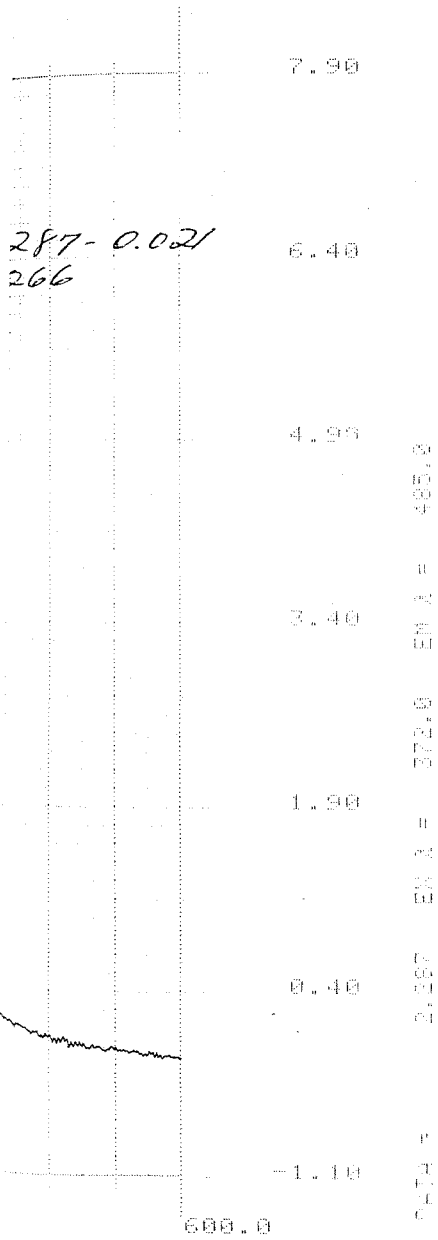
*Tablet 1 - Test*

*Corrected Emission*



Wavelength (nm)





7.90

6.40

4.90

3.40

1.90

0.40

-1.10

600.0

DATA = 510.0 EX A = 570.0 EM A = 485.0

7.90 *Tablet 2 - Test 2*

6.40

4.90

3.40

1.90

0.40

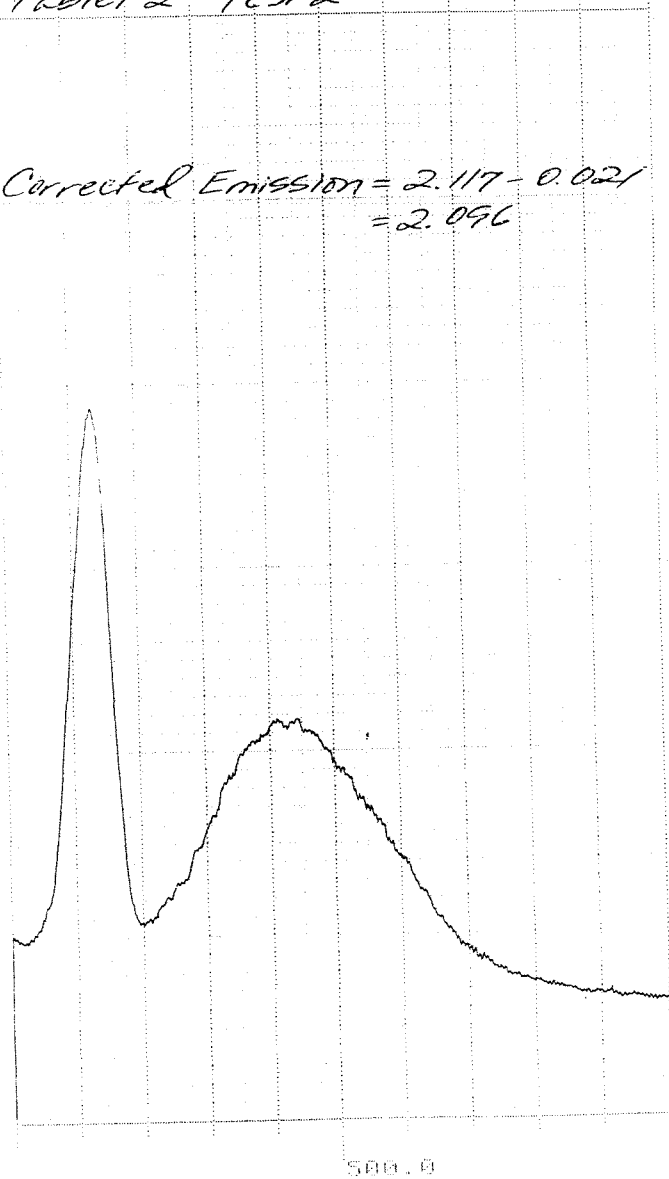
-1.10

200.0

500.0

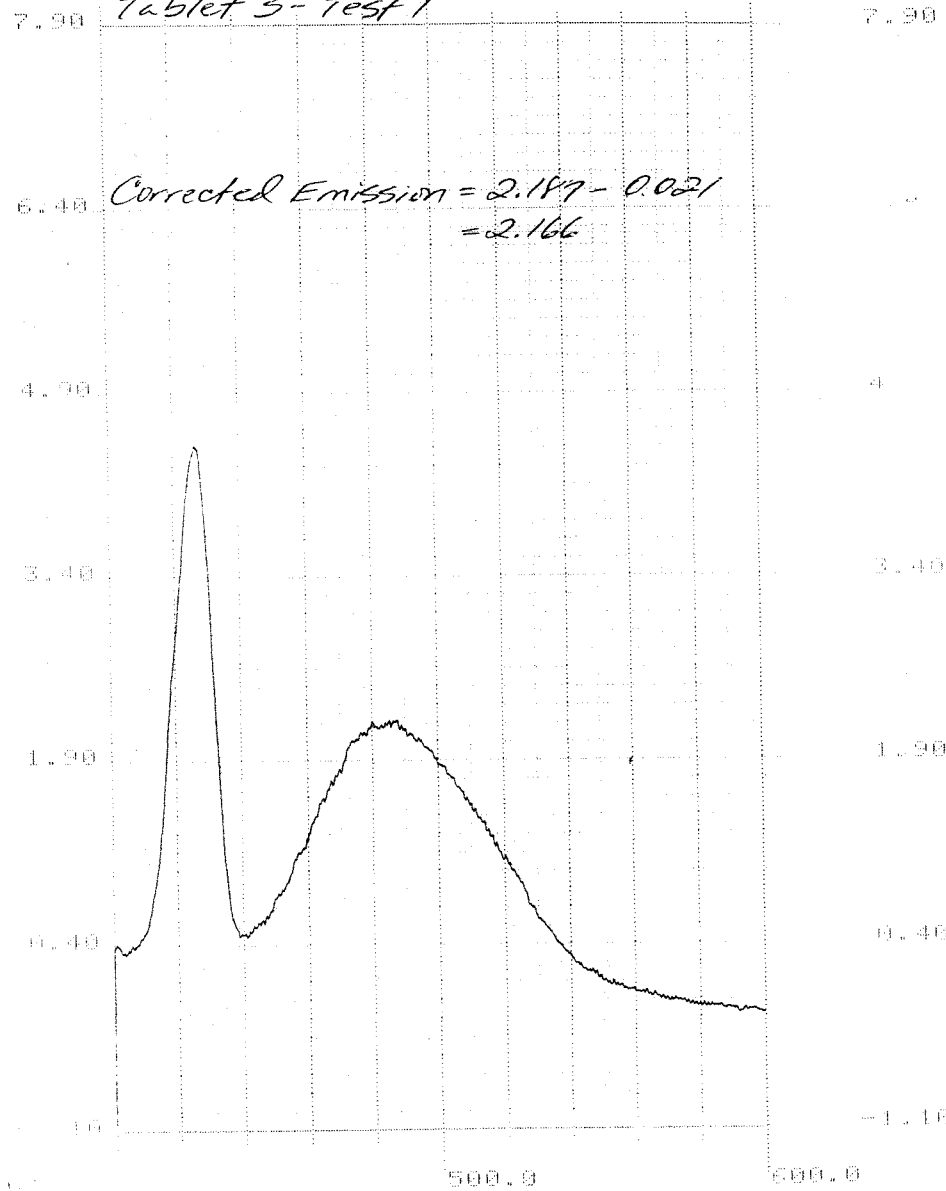
600.0

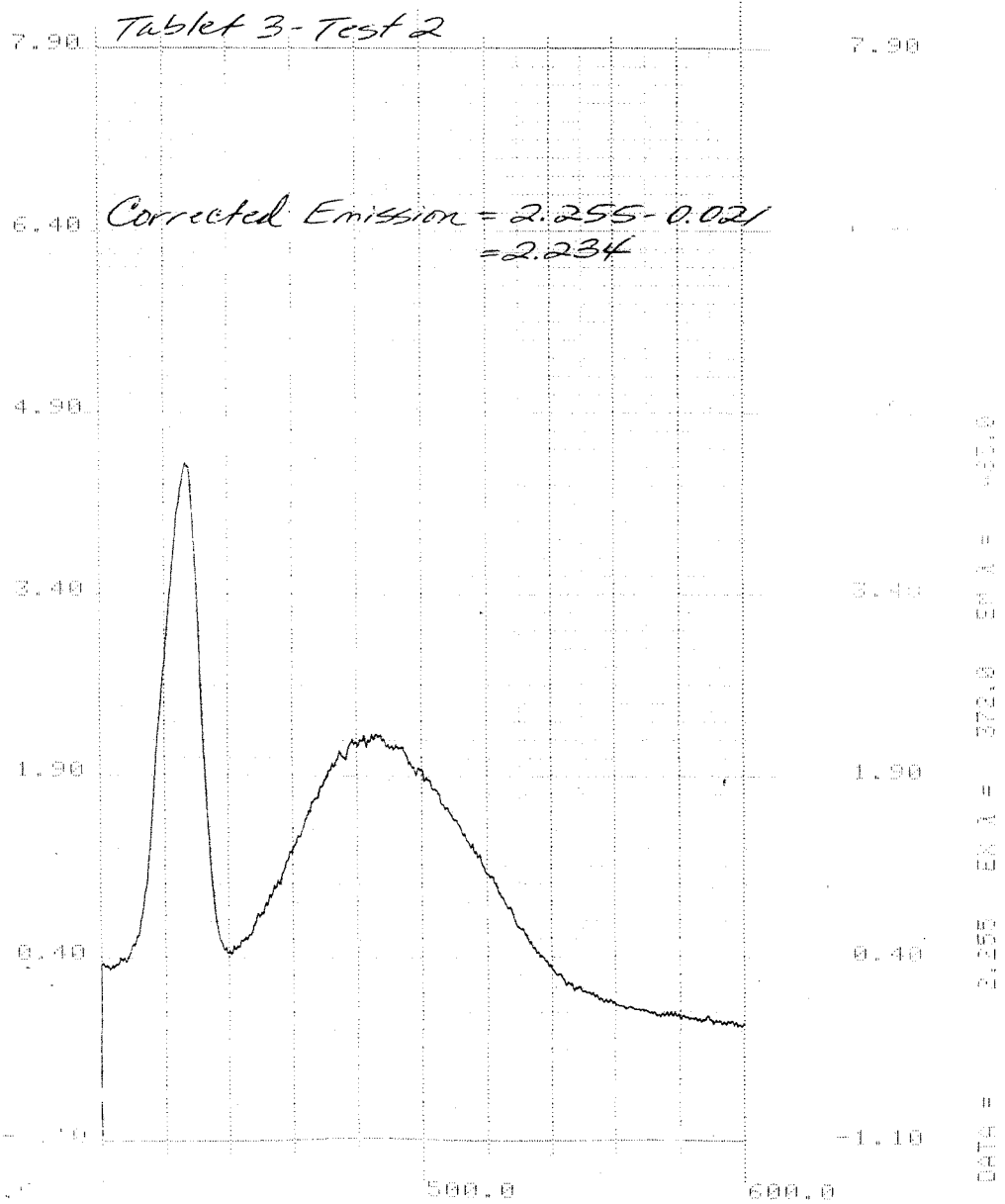
*Corrected Emission = 2.117 - 0.021  
= 2.096*



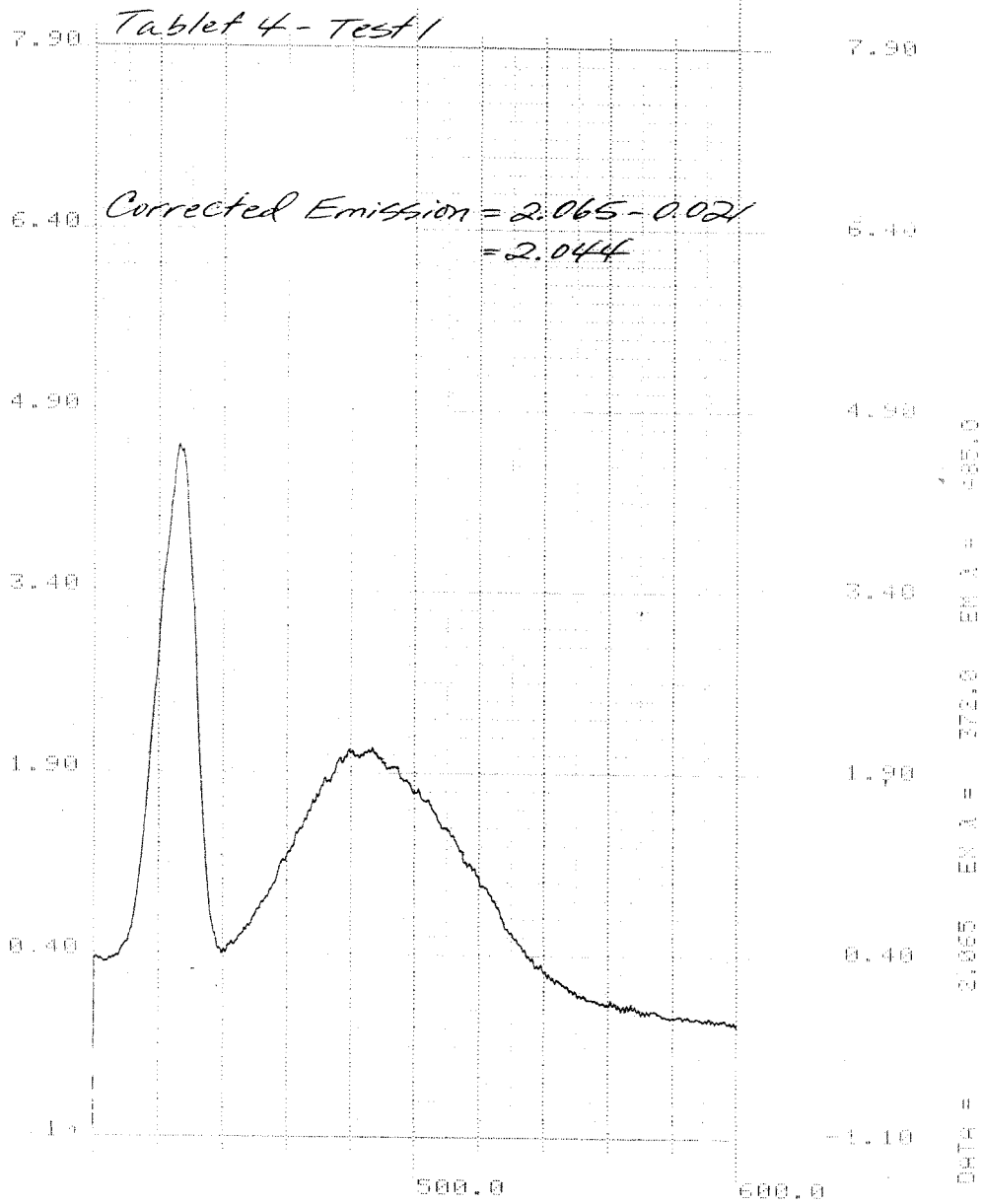
Tablet 3 - Test 1

$$\text{Corrected Emission} = 2.187 - 0.021 = 2.166$$



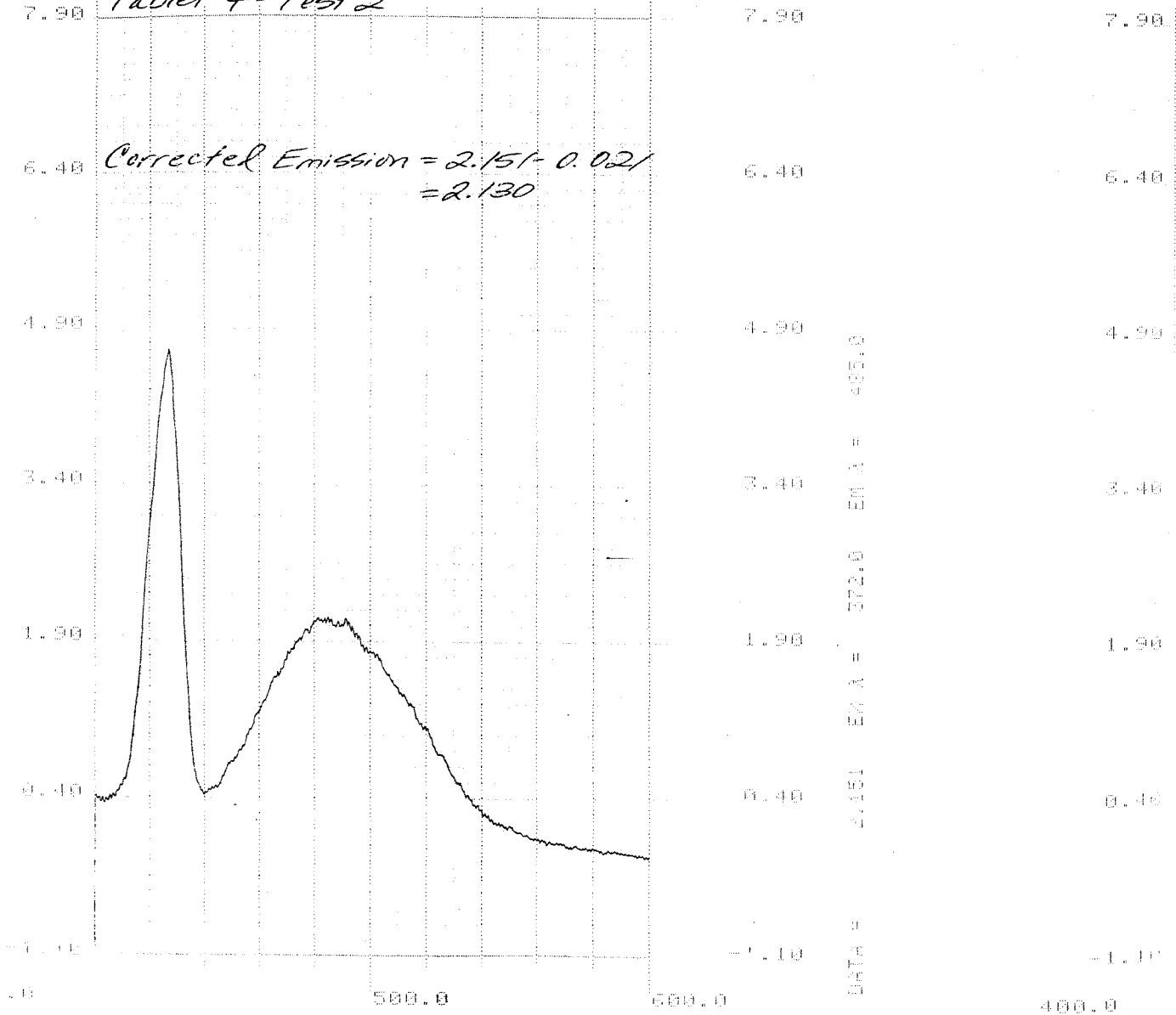






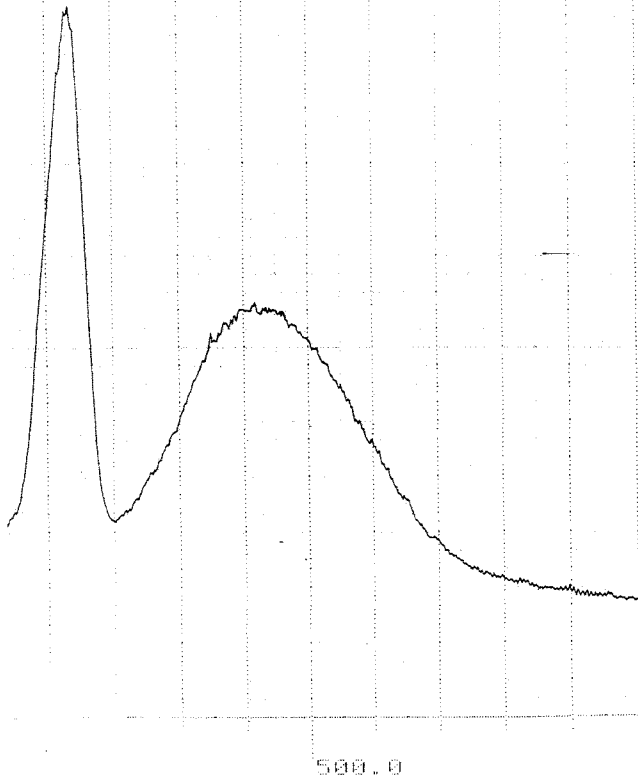
Tablet 4 - Test 2

Corrected Emission =  $2.151 - 0.021$   
 $= 2.130$



Tablet 5- Test 1

$$\text{Corrected Emission} = 2.208 - 0.021 \\ = 2.187$$



7.90

6.40

4.90

3.40

1.90

0.40

-1.10

405.0  
372.0  
340.0  
310.0  
280.0  
250.0  
220.0  
190.0  
160.0  
130.0  
100.0  
70.0  
40.0  
20.0  
0.0  
-10.0  
-20.0  
-30.0  
-40.0  
-50.0  
-60.0  
-70.0  
-80.0  
-90.0  
-100.0

7.90 Tablet

6.40 Corrected

4.90

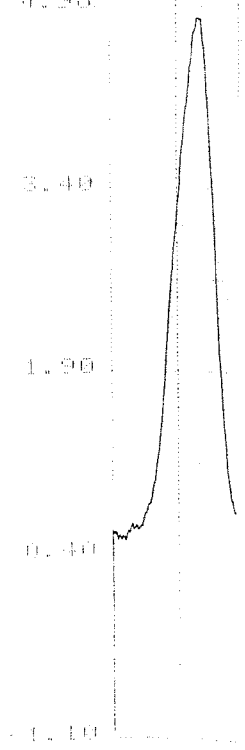
3.40

1.90

0.40

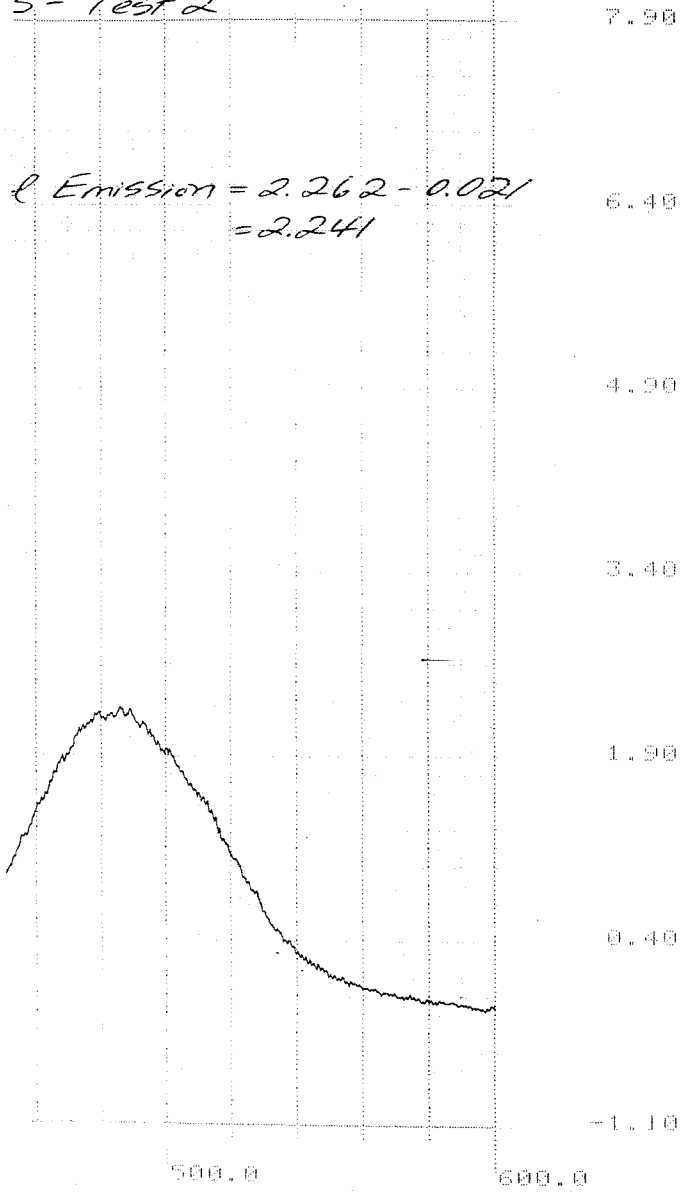
-1.10

400.0



5- Test 2

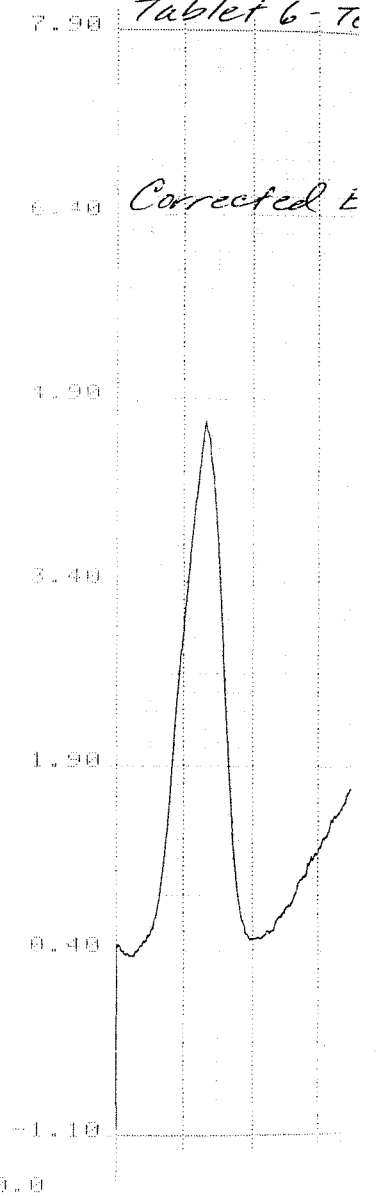
$$\begin{aligned} \text{Emission} &= 2.262 - 0.021 \\ &= 2.241 \end{aligned}$$

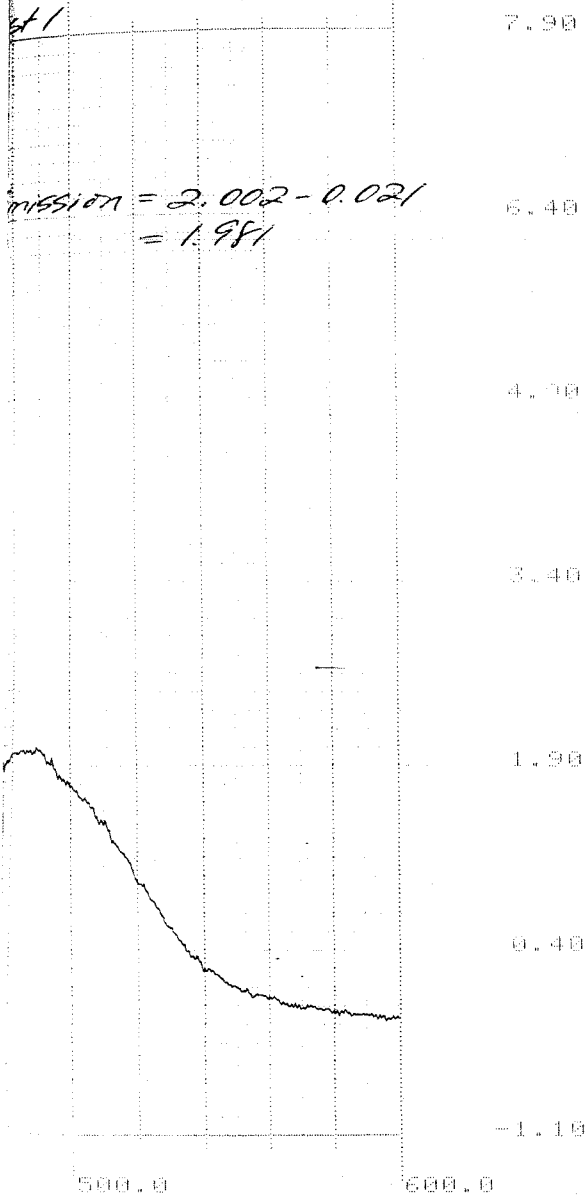


Wavelength = 572.0 nm  $\lambda = 495.0$

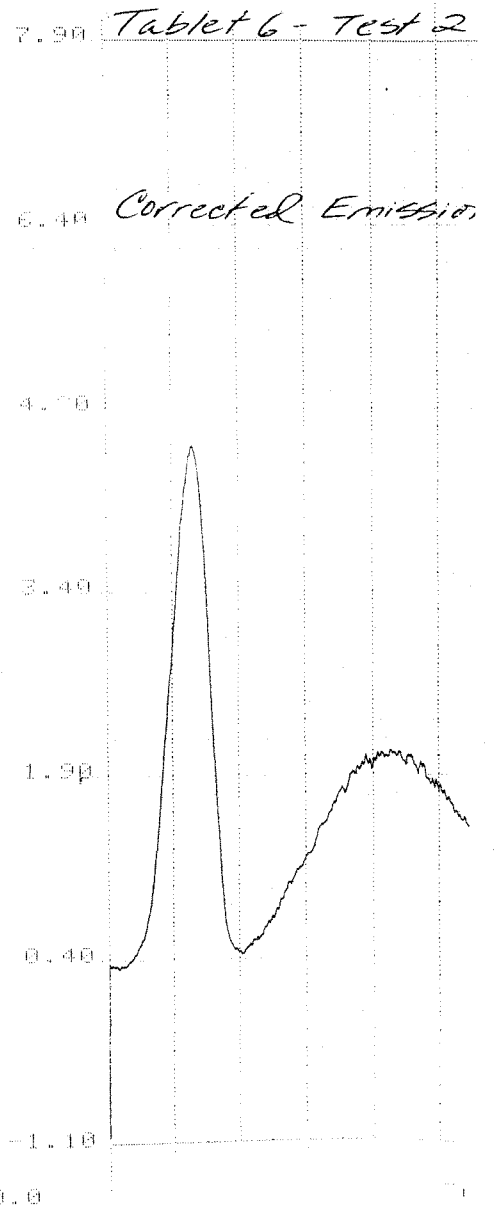
Tablet 6-7c

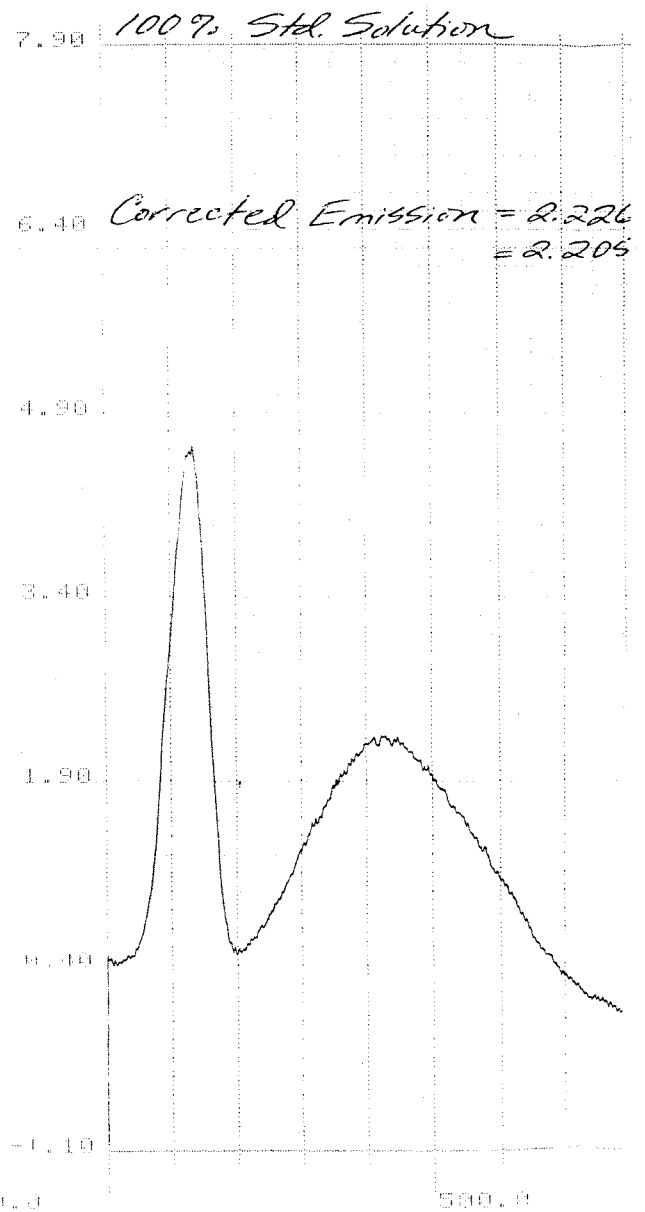
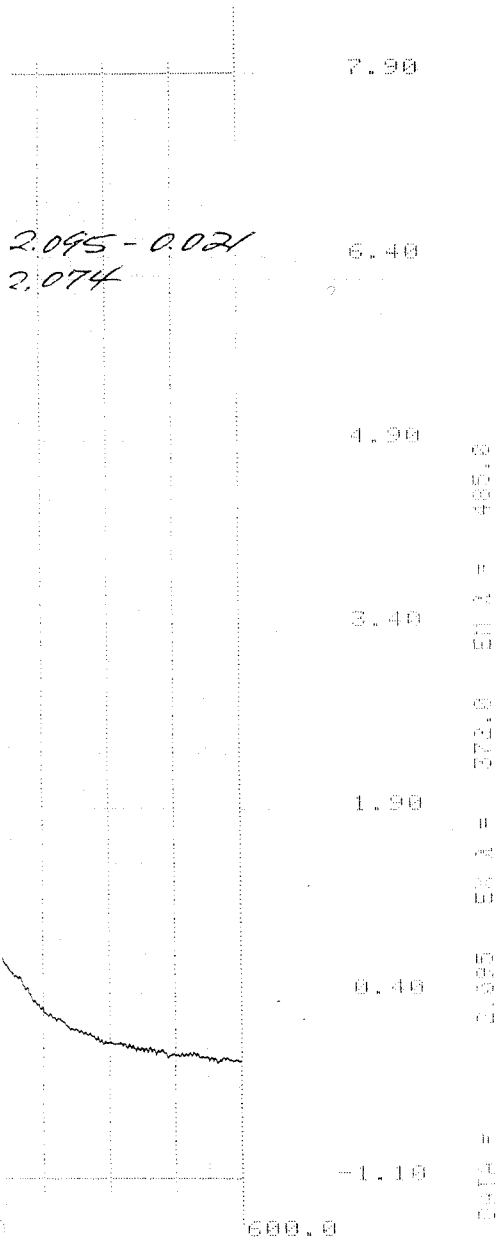
Corrected E

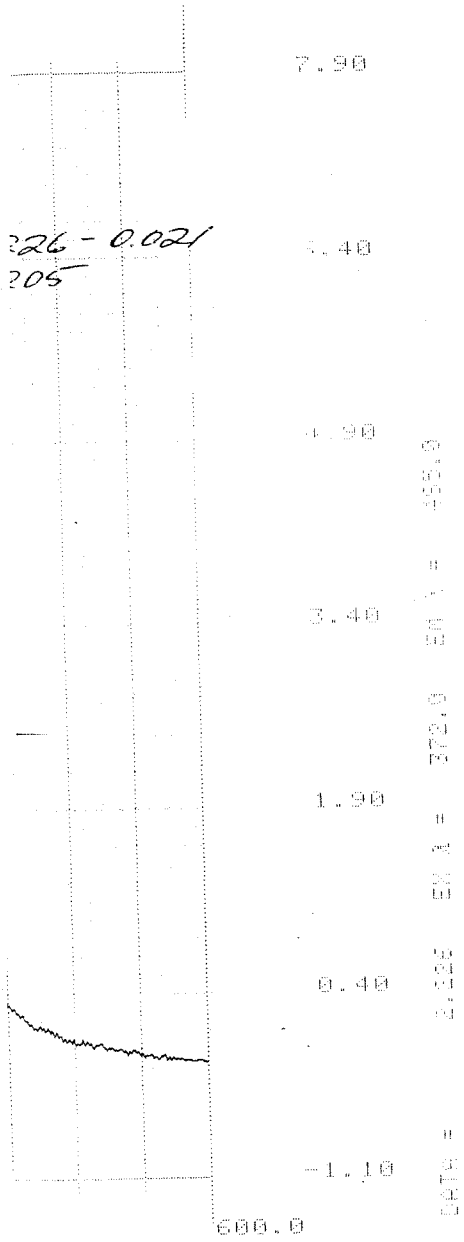




WAVELENGTH (nm) = 500.0 520.0 540.0 560.0 580.0 600.0







Digoxin Tablets (0.125 mg)  
 Spl.# 453913  
 2/27/08  
 VF

Labeling

